(1) Supreme Court, U.S.
FILED

No. 94-941971 JUN 2 5 1995

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

SHILEY INC.; Hospital Products Group, Inc.,
(Formerly Howmedica, Inc.); Pfizer, Inc.,

Petitioners,

—against—

NINA MICHAEL,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR WRIT OF CERTIORARI

DAVID KLINGSBERG
KAYE, SCHOLER, FIERMAN,
HAYS & HANDLER
425 Park Avenue
New York, New York 10022
(212) 836-8000

Counsel of Record for Petitioners

105pp

QUESTIONS PRESENTED

1. Does the express preemption provision of § 360k(a) of the Medical Device Amendments of 1976, which prohibits state requirements relating to the safety or effectiveness of a medical device that are different from or additional to the federal requirements, preempt common law claims for:

- fraud, that would impose requirements of state law to test a manufacturer's communications concerning the risks and benefits of an FDA-approved and regulated medical device, and
- breach of warranty, that would impose requirements of state negligence law to test the manufacturing procedures for an FDA-approved and regulated medical device?

2. Does this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), which denied preemption for certain common law claims because they did not satisfy the "based on smoking and health" limitation in the preemption provision of the Public Health Cigarette Smoking Act of 1969, permit common law claims to escape preemption under the broader preemption provision of the Medical Device Amendments and other statutes that have no comparable limitation?

RULE 29.1 LISTING

Pursuant to Sup. Ct. R. 29.1, petitioner Pfizer Inc. has no parent company. Petitioner Shiley Incorporated is a wholly owned subsidiary of petitioner Pfizer Inc. Petitioner Hospital Products Group is an unincorporated division of petitioner Pfizer Inc.

Petitioner Pfizer Inc. has the following non-wholly owned subsidiaries: Pfizer Biogal L.L.C.; Pfizer C. & G. Inc.; Pfizer Egypt S.A.E.; Pfizer Limited (Ghana); Pfizer Limited (India); PT Pfizer Indonesia; Livestock Feeds PLC; Pfizer Products PLC; Pfizer Laboratories Limited; Pfizer Korea Limited; Pfizer Holding Und Verwaltungs G.m.b.H.; Howmedica Iberica S.A.; Rovi Farma S.A.

TABLE OF CONTENTS

	PAGE
QUESTIONS PRESENTED	i
RULE 29.1 LISTING	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	1
CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	4
A. Factual and Procedural Background	4
B. The District Court's Opinion	6
C. The Court of Appeals' Opinion	7
REASONS FOR GRANTING THE WRIT	8
I. INTRODUCTION AND SUMMARY.	8
II. THE DECISION BELOW CREATED A SPLIT IN THE CIRCUITS.	10

PAGE

III. THE DECISION BELOW, INSOFAR AS IT HELD CLAIMS UNDER TWO THEORIES NOT PREEMPTED, IGNORED THE PLAIN LANGUAGE OF § 360k(a), MISINTERPRETED *CIPOLLONE* AND CONFLICTS WITH OTHER PREEMPTION DECISIONS OF THIS COURT. 12

A. Fraud claim based on communications to doctors 12

1. 360k(a)(2) 13

a. Relates to safety or effectiveness of the device. 13

b. Relates to any other matter included in a requirement applicable to the device under this chapter. 17

2. 360k(a)(1): Different from, or in addition to, FDA requirements 19

B. Breach of Express Warranty 20

CONCLUSION 23

TABLE OF AUTHORITIES

Cases:

PAGE

American Airlines v. Wolens, 115 S. Ct. 817 (1995)...22, 23

Anguiano v. E.I. Du Pont De Nemours & Co., 44 F.3d 806 (9th Cir. 1995)..... 12

Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) .....*passim*

Coulter v. E.I. Du Pont De Nemours & Co., No. 93-16008 *et. al.*, 1995 WL 11126 (9th Cir. 1995) 12

Dandridge v. Williams, 397 U.S. 471 (1970) 8

Duncan v. Iolab Corp., 12 F.3d 194 (11th Cir. 1994).. 12

Freightliner v. Myrick, 115 S. Ct. 483 (1995 10

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994).....10, 12

Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990) 9, 13, 15, 17, 18, 19

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 9, 10, 11, 12

Kordell v. United States, 335 U.S. 345 (1948)..... 19

Lamontagne v. E.I. Du Pont De Nemours & Co., 41 F.3d 846 (2d Cir. 1994) 12

Martello v. Ciba Vision Corp., 42 F.3d 1167 (8th Cir. 1994), *petition for cert. filed*, 63 U.S.L.W. 3819 (U.S. May 8, 1995) (No. 94-1832).....9, 11, 12

Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) 12

PAGE

Morales v. Trans World Airlines, 112 S. Ct. 2031 (1992) 9, 13, 14, 17, 18, 19

National Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) 12

Reeves v. Acromed Corp., 44 F.3d 300 (5th Cir. 1995), *cert. denied*, 1995 WL 258615 (U.S. May 30, 1995) (No. 94-1754) 10, 12

Saudi Arabia v. Nelson, 113 S. Ct. 1471 (1993) 16

Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) 10

Stamps v. Collogen Corp., 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, 114 S. Ct. 86 (1994) .. 9, 10, 11, 12

Constitutional Provisions, Statutes and Regulations:

U.S. Const., art VI 2, 8

21 U.S.C. § 301 *et seq.* 4

21 U.S.C. § 360c *et seq.* 4

21 U.S.C. § 360h(a) 2, 18, 20

21 U.S.C. § 360k 6, 18, 12, 19, 20

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(a)(1) 12, 13, 19, 20

21 U.S.C. § 360k(a)(2) 12, 13, 17, 19

21 C.F.R. § 814.20(b)(10) 2, 19, 20

21 C.F.R. § 814.39(a)(2) 2, 19, 20

Miscellaneous:

S. Rep. No. 94-33, 94th Cong., 2d Sess. (1975) 4, 5

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

No. 94-____

SHILEY, INC., Hospital Products Group, Inc.,
(Formerly Howmedica, Inc.); Pfizer, Inc.,

Petitioners,

—against—

NINA MICHAEL,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the Third Circuit, App. at 1a-38a,[1] is reported at 46 F.3d 1316. The opinion of the district court, App. at 39a-66a, is reported at Prod. Liab. Rep. (CCH) ¶ 13,893.

JURISDICTION

The judgment of the Court of Appeals was entered on February 7, 1995. A timely petition for rehearing and a sug-

[1] Citation to "App. at ___" refers to the appendix to this petition.

gestion for rehearing *en banc* were denied on March 7, 1995. App. at 67a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The United States Constitution, Article VI in pertinent part provides:

> "This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

21 U.S.C. § 360k(a) in pertinent part provides:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360h(a) in pertinent part provides:

> "If the Secretary determines that—
>
> (1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk."

21 C.F.R. § 814.20(b)(10) in pertinent part provides:

"[A] PMA shall include[2]:

(10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling . . . ."

21 C.F.R. § 814.39(a)(2) in pertinent part provides:

"(a) After FDA approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA . . . has advised that an alternative submission is permitted. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include but are not limited to the following

---

[2] "PMA" is an abbreviation for "pre-market approval." Approval of a PMA application constitutes FDA approval to market a device.

types of changes if they affect the safety or effectiveness of the device:

(2) Labeling changes."

STATEMENT OF THE CASE

In this case, the Third Circuit—in conflict with three other Circuits that have considered the issue—declined to give proper effect to the express preemption provision of the 1976 Medical Device Amendments ("MDA")[3] to the Federal Food, Drug and Cosmetic Act.[4] Plaintiff-respondent Nina Michael seeks to establish state law requirements for a medical device approved and regulated by the U.S. Food and Drug Administration ("FDA"). The MDA by its express language prohibits states from establishing any requirement "different from, or in addition to" the federal requirements applicable to the device under the MDA, where such state requirement relates either to the safety or effectiveness of the device, or to any other matter included in the federal requirements. 21 U.S.C. § 360k(a).

A. Factual and Procedural Background

The MDA replaced state regulation of medical devices with a uniform system of federal regulation by the FDA. Congress had two aims in enacting the MDA. First, it sought to encourage the fledgling medical device industry in its development of new and much-needed products: "[A]n increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development." S. Rep. No. 94-33, 94th Cong.,

---

[3] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C.A. § 360c *et seq.* (Supp. 1995)).

[4] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C.A. § 301 *et seq.* (1972 & Supp. 1995)).

2d Sess., at 2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. Second, Congress "want[ed] to be sure that the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices." S. Rep. No. 94-33, 94th Cong., 2d Sess., at 2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. To accomplish these objectives, Congress included in the MDA extensive regulatory requirements, which were to be administered by the FDA, and the express preemption provision in § 360k(a). The preemption provision enabled manufacturers to develop and sell new medical devices in reliance on FDA requirements and approvals, without fear of second-guessing by the states—including the state courts.

The medical device at issue here is an artificial heart valve, known as the Bjork-Shiley Convexo-Concave valve ("C/C valve") manufactured by defendant-petitioner Shiley Incorporated ("Shiley"), a wholly owned subsidiary of defendant-petitioner Pfizer Inc. ("Pfizer").[5] This artificial heart valve is a lifesaving medical device designed for implant inside the human heart to replace diseased and failing parts of the natural organ.

Plaintiff's claims are based on her elective replacement of a normally functioning C/C valve; she does not contend that her C/C valve failed or malfunctioned in any way. App. at 58a. In November, 1982 plaintiff underwent open-heart surgery to replace her diseased and failing natural heart valve with a C/C valve. App. at 5a, 40a. Thereafter, plaintiff learned that some other C/C valves, similar to hers, had failed or malfunctioned. App. at 6a, 40a. Plaintiff alleged that such information caused her emotional distress due to concern that her own C/C valve might fail at some unspecified time in the future. App. at 40a. In June, 1992, although her C/C valve had been sustaining her life for nearly ten years and continued to do so without incident, plaintiff underwent surgery to replace

---

[5] Defendant-petitioner Hospital Products Group (formerly known as Howmedica Inc.) is an unincorporated division of Pfizer Inc.

her C/C valve with another manufacturer's artificial heart valve. App at 40a-41a. Upon examination after removal, the C/C valve was intact. App. at 6a, 41a. Plaintiff concedes that it was not defective. App. at 58a. "Until the time it was removed, Ms. Michael's [C/C] heart valve was functioning properly and there was no indication that it had malfunctioned or would have malfunctioned in the future." App. at 41a. Plaintiff acknowledged that she has no medical problems today that she attributes to her reoperation. Plaintiff's Deposition at 140.

Plaintiff brought suit on March 9, 1993 in the Philadelphia County Court of Common Pleas. Based upon diversity of citizenship, defendants removed to the United States District Court for the Eastern District of Pennsylvania. App. at 39a & n.1.

B. The District Court's Opinion

Plaintiff's complaint seeks damages for alleged emotional distress and the pain of the replacement surgery. She seeks recovery under a variety of legal theories including strict liability, negligence, fraud and breach of express and implied warranty. App. at 39a. Defendants moved for summary judgment dismissing the Complaint. Defendants moved on the grounds of federal preemption as to all claims and theories other than breach of express warranty, and also sought summary judgment as to the entire complaint for failure to state a claim under state law. App. at 40a. The state law ground of the motion is not at issue on this Petition.

Relying on this Court's preemption decision in *Cipollone v. Liggett Group Inc.*, 112 S. Ct. 2608 (1992) and the decisions of three Courts of Appeals in cases involving preemption under the MDA, the District Court held that all claims as to which defendants had moved were preempted.

The district court first reviewed the applicable principles of preemption under the MDA. It held that the "ordinary English" of the MDA § 360k constitutes an express preemption provision. App. at 45a. It then applied *Cipollone* to hold

that the MDA's prohibition of different or additional state "requirements" encompassed state common law claims asserted in a lawsuit. App. at 46a-47a. Next, the district court held that the extensive federal regulatory requirements that the FDA imposed on medical devices such as the C/C valve through its pre-market approval process and post-approval regulations "are 'requirements' within the meaning of § 360k(a) that preempt Pennsylvania law claims involving the Shiley heart valves." App. at 50a.

The district court then analyzed each of plaintiff's claims to determine if it fell within the preemption provision of § 360k(a). It held that the manufacturing-based claims (negligence and strict liability) were preempted because there were FDA requirements as to the C/C valve's design and manufacture, and plaintiff's claims would require a jury "to rule that defendants should have redesigned the product, used different manufacturing methods . . . or be subject to tort liability." App. at 51a-52a. The district court found the fraud and failure to warn claims to be preempted because, *inter alia*, a "finding of a failure to warn . . . would 'impose a requirement on [defendants] to change [their] packaging or labeling,' " App. at 52a, and the MDA "pervasively regulates defendants' marketing behavior through its standards and regulation of labeling, packaging and manufacturing." App. at 54a-55a. The implied warranty of merchantability claim was held preempted because it would impose requirements by operation of state law that relate to and are additional to federal requirements, and relate to the packaging and labeling requirements for the C/C valve. App. at 53a.

C. The Court of Appeals' Opinion

On plaintiff's appeal, the Third Circuit affirmed the district court's preemption holdings as to plaintiff's claims under theories of strict liability; negligent design, manufacture and failure to warn; fraud on the FDA; and implied warranty of merchantability. App. at 2a.

The Third Circuit reversed the district court's dismissal of the claims under two additional theories:

- Fraud on the medical community. The Court of Appeals held that § 360k did not preempt a claim based on a fraud theory which alleged that defendants had disseminated misleading communications to the medical community. App. at 2a.
- Breach of express warranty. The district court had granted summary judgment on this claim under state law, which the Court of Appeals reversed. The Court of Appeals then rejected preemption as an alternate ground for affirming the summary judgment, holding that § 360k did not preempt plaintiff's express warranty claim.[6] App. at 14a, 21a.

After the Third Circuit's decision, defendants timely moved for rehearing (with a suggestion for rehearing *en banc*) as to the holdings against preemption of claims under these two theories. App. at 67a. The motion for rehearing was denied on March 7, 1995, although one member of the Court would have granted rehearing. *Id.*

REASONS FOR GRANTING THE WRIT

I. INTRODUCTION AND SUMMARY

Federal preemption is an issue going to the core of the Constitution and our federal system. It is grounded in the Supremacy Clause, which provides: "This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI.

---

[6] On appeal, the prevailing party may assert any ground in support of its judgment, "whether or not that ground was relied upon or even considered by the trial court." *Dandridge v. Williams*, 397 U.S. 471, 475 n.6 (1970). Defendants asserted preemption of the claim based on breach of express warranty.

In holding claims under two theories not preempted, the decision below ignored the mandate of the MDA preemption provision, § 360k(a), and also ignored two decisions of this Court which broadly defined and applied preemption language similar to that of the MDA. *Morales v. Trans World Airlines*, 112 S. Ct. 2031 (1992); *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990).

Importantly, the Third Circuit's decision also misread and misapplied *Cipollone*. The court below failed to realize that when this Court in *Cipollone* held certain claims not preempted, it did so based on the specific language of the Public Health Cigarette Smoking Act of 1969 ("Smoking Act") preemption provision; and that this holding did not foreclose preemption of claims under a different, broader preemption statute such as § 360k(a) of the MDA. By importing into the MDA a restrictive clause from the Smoking Act preemption provision that has no counterpart in § 360k(a), the Third Circuit opened the door to full-scale investigation and regulation by state courts and lay juries of the relative benefits and risks of artificial heart valves and other medical devices, including inquiry into the intricacies of the manufacturing process which the FDA regulates. That is precisely the kind of state second-guessing that Congress sought to avoid through § 360k(a).

The decision below is directly contrary to prior decisions of the First, Fifth and Eighth Circuits.[7] By creating a split in the circuits, the Third Circuit's decision destroys geographic uniformity in this important area of federal law, in addition to thwarting the substantive uniformity of medical device regulation that Congress mandated by expressly preempting state requirements.

---

[7] *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *petition for cert. filed*, 63 U.S.L.W. 3819 (U.S. May 8, 1995) (No. 94-1832).

What is more, the Third Circuit's erroneous application of *Cipollone* has potential impact beyond the MDA. The same error could lead courts improperly to restrict the scope of other preemption statutes that broadly prohibit state requirements relating to the federally regulated area, such as the preemption provisions in the Employee Retirement Income Security Act and the Airline Deregulation Act.

For all these reasons, certiorari is warranted. *Cipollone* has been a seminal decision, figuring in some 177 federal and state court decisions to date.[8] Just as this Court recently clarified another aspect of *Cipollone* (concerning the relationship between express and implied preemption),[9] clarification is needed here to prevent other courts from making the same error that the Third Circuit made below. Although this Court has denied certiorari in the five prior medical device preemption cases that have come up since *Cipollone*,[10] this case is different. In each of those prior cases, the Courts of Appeals had held that the MDA preempted the claims at issue; while here, the decision below allowed the pursuit of state law claims relating to the safety and effectiveness of a regulated medical device. Accordingly, while there was no need previously to correct an error, there is now.

II. THE DECISION BELOW CREATED A SPLIT IN THE CIRCUITS.

The court below created a conflict among the circuits with respect to each of the two claims that it held not to be preempted. The holding permitting plaintiff's claim under a the-

---

[8] *See*, App. at 68a-74a.

[9] *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995).

[10] *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 1995 WL 258615 (U.S. May 30, 1995) (No. 94-1754); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992).

ory of fraud on the medical community—*i.e.*, that defendants' communications to doctors misrepresented the valve's risks and overstated its benefits, App. at 24a-25a—conflicts with decisions of the First and the Fifth Circuits. In *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), the First Circuit held that misrepresentation and failure to warn claims are preempted because they would impose state requirements on the product's FDA-approved packaging or labeling, which the defendant "cannot be forced to change . . . by virtue of these state law damage claims." 983 F.2d at 1136. As the Court explained, a claim based on a fraud theory "is, at bottom, a failure to warn claim," which also is preempted for the same reasons. *Id.* at 1136. The Fifth Circuit, in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), has also held that the MDA preempts failure to warn claims.

In allowing plaintiff's claim under an express warranty theory, the decision below conflicts with decisions of the First and Eighth Circuits. The First Circuit held in *King* that an express warranty claim based on "the FDA-approved labeling and packaging" is preempted because the label's language is subject to FDA requirements and allowing the claim "effectively would impose additional or different requirements on [the] labeling and packaging." 983 F.2d at 1135. The same is true here of Shiley's warranty that reasonable care was used in manufacturing plaintiff's valve; her claim "effectively would impose additional or different requirements on" the manufacturing process. The Eighth Circuit, in *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *petition for cert. filed*, 63 U.S.L.W. 3819 (U.S. May 8, 1995) (No. 94-1832), also held that that an express warranty claim was preempted by the MDA.

Certiorari is needed to resolve these circuit conflicts. No purpose would be served by deferring certiorari to await further development of the appellate case law, because preemption of medical device claims has now been well-aired in the Courts of Appeals. Since this Court handed down *Cipol-*

lone in 1992, there have been twelve decisions by six Courts of Appeals concerning preemption of common law claims by § 360k of the MDA.[11] This Court should grant certiorari to ensure national uniformity in this important area where Congress, by enacting § 360k, has expressly decreed that federal standards should govern.

III. THE DECISION BELOW, INSOFAR AS IT HELD CLAIMS UNDER TWO THEORIES NOT PREEMPTED, IGNORED THE PLAIN LANGUAGE OF § 360k(a), MISINTERPRETED *CIPOLLONE* AND CONFLICTS WITH OTHER PREEMPTION DECISIONS OF THIS COURT.

A. *Fraud claim based on communications to doctors*

The controlling statutory language in the MDA provides that for a state requirement to be preempted, two elements must be fulfilled: one in 21 U.S.C. § 360k(a)(1), and one of two alternatives in § 360k(a)(2).[12] To satisfy § 360k(a)(2), the

---

[11] *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995); *Coulter v. E.I. Du Pont De Nemours & Co.*, No. 93-16008 *et. al.*, 1995 WL 11126 (9th Cir. 1995); *Michael v. Shiley. Inc.*, 46 F.3d 1316 (3d Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir. 1995), *cert. denied*, 1995 WL 258615 (U.S. May 30, 1995) (No. 94-1832); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Lamontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846 (2d Cir. 1994); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *petition for cert. filed*, 63 U.S.L.W. 3819 (U.S. May 8, 1995) (No. 94-1832); *Mendes v. Medtronic Inc.*, 18 F.3d 13 (1st Cir. 1994); *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

[12] Section 360k(a) provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(footnote continued on next page)

state requirement must relate to either the "safety or effectiveness of the device," or to "any other matter included in a requirement applicable to the device" under the MDA. To satisfy § 360k(a)(1), the state requirement must be "different from, or in addition to" any federal requirement. The Third Circuit erroneously found that the physician-fraud claim did not satisfy either prong of § 360k(a)(2), and therefore did not reach § 360k(a)(1).

1. 360k(a)(2)

Focusing on § 360k(a)(2), the Third Circuit concluded that the physician-fraud claim did not "relate to the safety or effectiveness" of the Shiley valve, App. at 25a, and "also" that it did not "relate[ ] to any other FDA requirement." App. at 26a. As the court below recognized, if a state requirement meets either one or the other of these two criteria, it satisfies 360k(a)(2). *Id.* Here, plaintiff's claim meets both of these criteria.

a. Relates to safety or effectiveness of the device

The Third Circuit's decision conflicts with this Court's definition and application of the words "relate to" in *Morales* and *Ingersoll-Rand*, as well as with the plain English meaning of the term. The Third Circuit erred by taking the restrictive "based upon smoking and health" clause in the Smoking Act preemption provision, which this Court defined and applied in *Cipollone*, and importing it into the MDA's much broader preemption provision. App. at 25a-26a.

On its face, plaintiff's physician-fraud claim plainly "relates to" safety or effectiveness. As the Third Circuit characterized the claim, it is that Shiley "knowingly mis-

---

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

represented the extent of the valve fracture problem" and "overstated the reduction in serious side effects." App. at 24a. Nothing could more directly "relate to" the "safety" of the valve than issues of "valve fracture" (a mode of mechanical failure of the valve with life-threatening consequences), and "serious side effects." The fraud count of the complaint itself is rife with allegations relating to safety and effectiveness of the C/C valve.[13]

Plaintiff's physician-fraud claim not only "relates to" the safety and effectiveness of the C/C valve as a matter of plain English, but also as a matter of law under controlling decisions of this Court. In *Morales* this Court broadly defined "relating to" in the preemption provision of the Airline Deregulation Act, which barred state regulation "relating to rates, routes, or services." 112 S. Ct. at 2037. In holding that states were preempted from enforcing deceptive advertising rules concerning airline advertising of rates, this Court stated:

> For purposes of the present case, the key phrase, obviously, is "relating to." The ordinary meaning of these words is a broad one—"to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with," Black's Law Dictionary 1158 (5th ed. 1979)—and the words thus express a broad pre-emptive purpose.

---

[13] Among the allegations of fraud included in the complaint are:

— "understatements in Shiley's reports of the strut fracture and failure rate when Shiley knew the . . . rate was significantly higher."

— "misleading and false information disseminated in connection with recalls. . . ."

— "omissions of . . . facts showing that [the C/C valve] had a history . . . of strut failure."

— "misleading statements about the number of complaints, history of failures and dangers conditions of the [C/C valve]."

Complaint at ¶ 38(a), (b), (c) & (f). In essence, these allegations all assert that Shiley did not warn Ms. Michael or her physicians of the risks associated with the C/C valve.

Id. The physician-fraud claim, as described above, inescapably has some bearing or concern, and indeed refers to the safety or effectiveness of the C/C valve.

In an earlier decision this Court similarly defined "relate to" as used in the preemption provision in the Employee Retirement Income Security Act of 1974 ("ERISA"), which prohibited state laws "insofar as they . . . relate to any employee benefit plan. . . ." *Ingersoll-Rand*, 498 U.S. at 138.

> "The pre-emption clause is conspicuous for its breadth." . . . Its "deliberately expansive" language was "designed to 'establish pension plan regulation as exclusively a federal concern.' " . . . The key to § 514(a) is found in the words "relate to."
>
> * * *
>
> Under this "broad common-sense meaning," a state law may "relate to" a benefit plan, and thereby be pre-empted, even if the law is not specifically designed to affect such plans, or the effect is only indirect.

Id. at 138-39 (citations omitted).

How then did the court below go astray from this controlling authority and find that plaintiff's claim under the physician-fraud theory did not relate to the safety or effectiveness of the device? The answer is that it applied the language of the Smoking Act preemption provision which was discussed in *Cipollone*. App. at 25a-26a. The Smoking Act preemption provision is much narrower than the MDA (and is also narrower than the Airline Deregulation Act and ERISA). This is not surprising in view of the limited purpose of the Smoking Act preemption provision, which is only to protect cigarette manufacturers from state requirements concerning the Congressionally mandated warning label. *Cipollone*, 112 S. Ct. at 2624.

Specifically, an additional element necessary for preemption under the Smoking Act is that the state requirement be " 'based on smoking and health.' " *Id.* As this Court stated, "[t]he Senate Report emphasized that the 'preemption of regulation or prohibition with respect to cigarette advertising is *narrowly phrased to preempt only State action based on smoking and health.*' " *Id.* at 2624 n.26 (citation omitted, emphasis in original). Applying that language, *Cipollone* denied preemption for certain fraud claims because this Court found that those claims were "based on . . . the duty not to deceive" rather than "based on smoking and health." *Id.* at 2624. As this Court has stated, the "natural meaning of the phrase 'based upon,' " requires "something *more than a mere* connection with, or *relation to*" the subject matter. *Saudi Arabia v. Nelson*, 113 S. Ct. 1471, 1477, 1478 (1993) (emphasis added).

The MDA contains no such limiting language. While the Smoking Act preempts only state requirements "*predicated* on a duty '*based on* smoking and health'," *id.* (emphasis added), the MDA has no corresponding limitation on the source or derivation of state requirements subject to preemption. Under § 360k(a), preempted state requirements can be "predicated on" or "based on" anything. The state requirements need only "relate to" (which means have some bearing on or concern with, or refer to) safety or effectiveness or to any federal requirement applicable to the device.

The Third Circuit's erroneous holding is contained in a paragraph at Appendix page 25a:

> Unlike Michael's strict liability claims which are based on a duty to produce safe products, Michael's fraud claims are based "on a more general obligation—the duty not to deceive." *Cipollone*, 112 S. Ct. at 2624. Thus, Michael's fraud claim does not relate to the safety or effectiveness of the Shiley valve.

In this paragraph, the court below erroneously applied *Cipollone*'s analysis of the Smoking Act's "based upon" lim-

itation, both to uphold preemption of Michael's strict liability claim and to deny preemption of her physician-fraud claim. The court thus indicated that its reason for finding the strict liability claims preempted was that they are "based on" a duty to produce safe products. There is, however, no element in § 360k(a) relating to the source of defendants' duty. By the same token, the source of the duty underlying plaintiff's physician-fraud claim cannot serve to deny preemption of that claim.

The second sentence of the above-quoted paragraph from the Third Circuit's decision does not follow from the first. Merely because the claim is "based upon" or "predicated on" a particular duty does not establish one way or the other whether it "relates to" safety or effectiveness. *Cipollone*'s application of the "based upon" limitation in the Smoking Act is not relevant to preemption under the MDA, and fails to support the Third Circuit's conclusion that plaintiff's physician-fraud claim does not "relate to" the safety or effectiveness of the C/C valve. The court below, in relying upon the "based on" aspect of *Cipollone*, misapprehended its application and ruled contrary to the meaning of "related to" as established in *Morales* and *Ingersoll-Rand*.[14]

b. Relates to any other matter included in a requirement applicable to the device under this chapter.

Regarding the second alternative test of § 360k(a)(2), the Third Circuit stated that it must determine whether the claim under the physician-fraud theory "relates to any other FDA requirement." App. at 26a. The court then proceeded, without any support in the controlling preemption decisions of this Court, to make an evidentiary inquiry into whether the FDA

---

[14] Moreover, the Third Circuit held that the physician fraud claim was not preempted because it was "based on" a general obligation not to deceive. App. at 25a. But this Court held in *Morales* that the "relates to" language covers requirements of "general applicability." 112 S. Ct. at 2038.

had pre-approved Shiley's advertising and promotional communications to doctors. App. at 26a-27a. Based on two journal articles, the Third Circuit concluded that the FDA was not "at that time" exercising its supervisory powers over such communications and that it was "[o]nly in the last few years" that it actively sought to control such communications. App. at 26a.

The Third Circuit's holding is contrary to the statute and to this Court's decisions. Section 360k(a) provides, as an alternative to the safety and effectiveness test, that the claim is preempted if it relates to any matter included in a requirement applicable to the device "under this chapter." In other words, the test is whether there are related requirements in the MDA itself, not whether the FDA sought in any particular instance or at any particular time to administer those requirements in a particular way, such as by pre-approval. As this Court held in *Morales* and *Ingersoll-Rand*, the "relating to" language is fulfilled if the claim has any bearing on or refers to matters included in the MDA requirement. *Morales*, 112 S. Ct. at 2037; *Ingersoll-Rand*, 498 U.S. at 138-39.

Plaintiff's physician-fraud claim satisfies this standard. As the Third Circuit elsewhere found, "The FDA had the power to force notification of a previously unknown risk under 21 U.S.C. 360h(a)." App. at 12a (footnote omitted). Thus, there are requirements in the MDA which enable the FDA, if it deems it appropriate, to force changes in or order corrections to communications to doctors and hospitals. At the same time, plaintiff's physician-fraud theory alleges that Shiley disseminated "misleading and false information" about the C/C valve, "understate[d]" the risks, and omitted facts. Complaint at ¶ 38. This plainly "relates to" notifications to physicians about the medical device at issue, which were subject to FDA requirements.

Further, FDA regulations for pre-market approval applications require submission of all proposed labeling including "any information, literature, or advertising that consti-

tutes labeling." 21 C.F.R. § 814.20(b)(10) (1992).[15] Proposed changes to such materials must also be submitted. 21 C.F.R. § 814.39(a)(2) (1992). Thus, literature and advertising are matters included in the FDA's pre-market approval requirements. Because the physician-fraud claim plainly "relates to" such matters, it satisfies the alternative test of § 360k(a)(2).

In short, the Third Circuit erred because it failed to analyze whether the claim under the physician-fraud theory "relates to" statutory requirements in accord with *Morales* and *Ingersoll-Rand*, but instead engaged in a factual inquiry as to when the FDA began to exercise authority in certain ways over certain types of communications. App. at 26a-27a.

2. 360k(a)(1): Different from, or in addition to, FDA requirements

In addition to satisfying both tests of § 360k(a)(2) (when only one is needed) as shown above, plaintiff's physician-fraud claim also satisfies § 360k(a)(1). Preemption is therefore mandated under the express terms of the statute.

The Third Circuit, in finding plaintiff's claim under the fraud on the FDA theory to be preempted, held that "[a] state law cause of action for fraud is a state imposed requirement," App. at 22a, and that "[u]nder § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA." App. at 23a.

The same is true of the physician-fraud claim. Because the Third Circuit erroneously found that this claim did not satisfy either of the two alternative prongs of § 360k(a)(2), it apparently saw no need to analyze the physician-fraud claim in terms of § 360k(a)(1). Section § 360k(a)(1) is, however, also satisfied here. The court below recognized that the C/C valve was subject to extensive FDA requirements. App. at 12a. Because the MDA contains requirements applicable to the

---

[15] Labeling includes materials that are not physically attached to or shipped with the product. *Kordell v. United States*, 335 U.S., 345, 349 (1948).

C/C valve, Michael's claim falls under the § 360k(a)(1) prohibition of any state requirement "which is different from, or in addition to, any requirement applicable under this chapter to the device. . . ." Thus, § 360k(a)(1) is satisfied here. A fortiori, § 360k(a)(1) is satisfied because the physican-fraud claim would impose state requirements on written communications about the valve that are different from, or in addition to, the federal requirements pertaining to notification, 21 U.S.C. § 360h(a), and labeling, 21 C.F.R. §§ 814.20(b)(10), 814.39(a)(2).

B. *Breach of Express Warranty*

Here again, in holding this claim not preempted, the Third Circuit misapprehended the terms of § 360k and this Court's decision in *Cipollone*.

The Third Circuit held that plaintiff's claims under negligent manufacturing and breach of *implied* warranty theories are preempted. App. at 13a-14a. It recognized that allowing the claim for breach of implied warranty "would require a finding that the heart valve's design was flawed, unreasonably dangerous, or poorly manufactured," which necessarily "depends upon the accepted standards for the design and manufacture of products in the state of Pennsylvania." App. at 14a. These standards, however, "may deviate from the FDA's determinations in the PMA process or from the FDA's 'good manufacturing practices,' which represent the agency's expert evaluation regarding the design and production of the Shiley valve." *Id.*

The express warranty claim was "based on Shiley's statement on its packaging that it 'warrants that reasonable care has been used in the manufacture of the device.' " App. at 14a. Because that warranty claim puts directly in issue whether defendant used reasonable care in manufacturing, it must be preempted for exactly the same reasons that led the Third Circuit to hold the negligent manufacturing and implied warranty claims preempted; *i.e.*, that state law manufacturing requirements may not be substituted for those of the FDA.

Nevertheless, despite its analysis and conclusion as to those claims, the Third Circuit held that the *express* warranty claim was not preempted.

Permitting a claim under the express warranty theory in this case would thwart the preemptive purpose of § 360k(a). The Third Circuit effectively recognized this when it stated in its discussion of the merits of plaintiff's express warranty claim that the "existence of a significant risk that the device will fail makes the product unsuitable for its purpose." App. at 28a-29a. A finding that the product is unsuitable would directly conflict with the FDA's determination when it granted pre-market approval for the C/C valve and allowed its continued use for at least eight years thereafter—*i.e.*, that the valve was safe and effective. In allowing the express warranty claim, therefore, the court permitted plaintiff to circumvent the express preemption provision and assert the very same claim raising the same issues that were preempted when stated under negligence and implied warranty theories.

As the court below recognized, the only basis for holding the express warranty claim not preempted would be if the claim is not based on a state requirement. App. at 15a. In holding that the claim did not involve a state requirement, the Third Circuit misapplied *Cipollone*.

The warranty claim in *Cipollone* was a general one where the "evidence of an express warranty consists largely of statements made in respondents' advertising." 112 S. Ct. at 2622. Under the Smoking Act, which preempted only "the imposition under state law of a requirement or prohibition based on smoking and health," this Court held that the " 'requirements' imposed by an express warranty claim are not 'imposed under state law,' but rather imposed *by the warrantor*." *Id.* (emphasis in original). This Court illustrated the point with an example of a warranty to pay the medical bills of a smoker who contracted emphysema. *Id.* "The duty to honor that promise" was not " 'imposed under state law,' but rather . . . undertaken by the manufacturer itself." *Id.*

This Court's analysis of the source of the duty ended the matter in *Cipollone* because courts could determine liability under the warranty that this Court posited with no need to make findings, or apply state standards, that would invade the preempted area of warnings about the hazards of smoking. In *American Airlines v. Wolens*, 115 S. Ct. 817 (1995), this Court explicity recognized the need to consider whether enforcement of a contractual obligation would implicate preempted state requirements. This Court held in *American Airlines* that the Airline Deregulation Act preemption provision did not bar claims to enforce airlines' contractual obligations to passengers. That statute preempts state regulation "related to a price, route or service of an air carrier. . . ." *Id.* at 821 n.3. This Court held that the contract claim there, involving terms for use of frequent flier miles, could be enforced "with no enlargement or enhancement based on state laws or policies external to the agreement." *Id.* at 826.

Here, however, the warranty is very different from that considered in *Cipollone* and the contractual obligation in *American Airlines*. Liability under the warranty here expressly turns on whether Shiley used reasonable care in manufacturing. *See* App. at 14a. That issue involves the very federal manufacturing requirements that the Third Circuit found to require preemption of the claims under other theories, and falls squarely within preempted subject matter under § 360k(a).

The Third Circuit failed to recognize that as plaintiff seeks to establish a breach of this warranty, regardless of the source of the warranty duty, prohibited state requirements, in the form of standards for what constitutes due care in manufacturing under state law, will come into play. The claim under this warranty theory necessarily invokes state requirements

relating to the safety and effectiveness of the C/C valve because, just as the Third Circuit acknowledged regarding the implied warranty claim, plaintiff must prove violation of "the accepted standards for the design and manufacture of products in the state of Pennsylvania." App. at 14a. Or, in the words of *American Airlines*, here the warranty *cannot* be enforced without "enlargement or enhancement based on state laws or policies external to the agreement." 115 S. Ct. at 826.

In short, allowing a claim under the express warranty here would subject Shiley's manufacturing processes to state standards and requirements that are different from or additional to the federal requirements and relate to the safety or effectiveness of the valve, in violation of § 360k(a). The claim is therefore preempted. Whether Shiley's manufacturing processes constituted reasonable care is a question exclusively in the province of the FDA, regardless of whether that question is raised under a legal theory of negligence, implied warranty or express warranty.

CONCLUSION

For the reasons stated above, to ensure correct application of *Cipollone*, to eliminate a split in the circuits and to correct the Third Circuit's disregard of the statutory language and this Court's controlling authority, this Court should grant Certiorari in this case.

Respectfully submitted

DAVID KLINGSBERG
KAYE, SCHOLER, FIERMAN,
HAYS & HANDLER
425 Park Avenue
New York, New York 10022
(212) 836-8000

Counsel of Record for Petitioners

APPENDIX

UNITED STATES COURT OF APPEALS
THIRD CIRCUIT

No. 94-1496

Argued Oct. 24, 1994
Decided Feb. 7, 1995

NINA MICHAEL,

Appellant,

—v.—

SHILEY, INC.; Hospital Products Group, Inc.,
(Formerly Howmedica, Inc.); Pfizer, Inc.

Gary Green (Argued), Sidkoff, Pincus & Green, Morton B. Wapner, David Kuritz, Wapner, Newman & Wigrizer, Philadelphia, PA, for appellant.

David Klingsberg (Argued), Maris Veidemanis, Kaye, Scholer, Fierman, Hays & Handler, New York City, John W. Frazier, IV, James A. Willhite, Jr., Montgomery, McCracken, Walker & Rhoads, Philadelphia, PA, for appellees.

BEFORE: STAPLETON, HUTCHINSON and GARTH, *Circuit Judges*.

OPINION OF THE COURT

GARTH, *Circuit Judge*:

This appeal requires that we determine how the Medical Devices Amendments of 1976, which amended the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 360-360rr, allocates authority between the states and the Food and Drug Administration. To be precise, we must decide whether 21 U.S.C. § 360k pre-empts Nina Michael's state law causes of action for negligent manufacture and design, strict product

liability, breach of the implied warranty of merchantability, breach of an express warranty, and common law fraud against Shiley Inc., the manufacturer of the Bjork-Shiley Heart Valve.

Applying the express pre-emption analysis defined by *Cipollone v. Liggett Group Inc.*, ___ U.S. ___, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), we conclude that § 360k pre-empts Michael's cause of action for negligence (both manufacturing and design), strict product liability, and breach of the implied warranty of merchantability. We also hold that Michael's complaint to the extent that it relies on fraud perpetrated by Shiley on the FDA is pre-empted. Finally, we hold that § 360k does not preclude Michael from pursuing common law causes of action for express warranty and for fraud to the extent that the fraud arises from Shiley's efforts to promote its product through letters to doctors and advertisements in medical journals.

Accordingly, while we will affirm the district court's pre-emption rulings as to Michael's negligence, strict product liability, and implied warranty claims, we will reverse the district court's summary judgment to the extent that it entered judgment against Michael on her express warranty and fraud claims.

I.

A.

Nina Michael's claims arise from the discovery in the past fifteen years that the outlet strut of the Bjork-Shiley 60 Degree Convexo-Concave Disc Heart Valve ("Shiley valve"), which was designed and manufactured by Shiley Inc., fractures in approximately one percent of the patients who received a Shiley implant. App. 200. These failures result from a weak strut mechanism and from poor manufacturing standards at Shiley's facilities. A strut failure leads inevitably to death or serious injury.

B.

The Shiley valve was one of the first medical devices to be approved under the 1976 Medical Device Amendments to the

Food Drug and Cosmetics Act of 1938 (the "MDA"), a comprehensive extension of the FDA's authority beyond medical drug manufacturers to medical device manufacturers. Pub.L. No. 94-295, 90 Stat. 539 (1976). Congress passed the Amendments in response to the harm caused by the Dalkon Shield, an unregulated medical device which resulted in serious injury to a large number of women.[1] Sen.Rep. No. 33, 94th Cong., 1st Sess. 2 *reprinted in* 1976 U.S.Code Cong. & Admin.News 1070, 1071. Through the MDA, Congress hoped "to assure the reasonable safety and effectiveness of medical devices intended for human use." H.Conf.Rep. No. 1090, 94th Cong., 1st Sess. 51 *reprinted in* 1976 U.S.Code Cong. & Admin.News 1070, 1103. To do so, it granted the FDA new broad powers to regulate medical devices, which powers are based on three statutory classifications.

Class I devices, such as tongue depressors, are devices which generally pose little or no threat to public health and are subject only to general controls on manufacturing. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as oxygen masks, pose a slightly greater risk of injury to patients, and accordingly, the MDA subjects them to performance standards, post market surveillance, guidelines for use and other appropriate controls. *See id.* § 360c(a)(1)(B). Class III devices, such as the Shiley valve, include all devices which are to be implanted into people, which are used to sustain life, or which pose a potentially unreasonable risk of injury. *See id.* § 360c(a)(1)(C).

Class III devices may not be marketed or sold until the sponsoring company obtains Premarket Approval (PMA) from the FDA. *Id.* § 360e. To obtain a PMA, the sponsor must submit "all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective," *id.* § 360e(c)(1)(A), a statement

---

[1] For a history of the harm which resulted from the Dalkon Shield, see *In re A.H. Robins Co.*, 880 F.2d 709, 710-12 (4th Cir.), *cert. denied sub nom., Anderson v. Aetna Casualty and Surety Co.*, 493 U.S. 959, 110 S.Ct. 377, 107 L.Ed.2d 362 (1989).

of the intended use of the product, a description of the expected manufacturing processes for the device, and any other information requested by the FDA. *Id.* § 360e(c)(1)(B)-(G). After review by a panel of medical experts, the FDA may approve the PMA.

The FDA retains continuing oversight over approved Class III devices. It requires manufacturers to report any deaths or serious injuries which result from the use of the product. *See* 21 C.F.R. § 803.24(c). It may require warning or instructions on the labels which accompany the product. 21 C.F.R. § 814.82. Finally, the FDA regulates the manufacture of the devices through the imposition of good manufacturing processes. 21 C.F.R. § 820.100-820.101. The only remedial power granted to the FDA is the power to require the sponsor of the product to notify the public of a newly discovered danger posed by the product, order the company to replace the device, or order the company to refund the purchase price to the patient. The FDA can take these actions only if it determines that the device presents an unreasonable risk of substantial harm to the public. 21 U.S.C. § 360h(a). The act does not permit the FDA to require companies to compensate victims for their medical expenses or for the pain and suffering resulting from a device failure.

C.

Shortly after the passage of the MDA, Shiley applied for Premarket Approval (PMA) to market the Shiley valve. At the time, the FDA's procedures for PMA applications had not been finalized, *see* 51 Fed.Reg. 26364 (July 22, 1986) (defining PMA procedures), and thus the Shiley application did not receive the same organized and comprehensive evaluation that might be expected today. Sen. Comm. on Energy & Commerce, 101st Cong., 2d Sess., The Bjork-Shiley Valve: Earn as You Learn 20-22 (Comm.Print 1990) [hereinafter Energy & Commerce Report]. For example, evidence of the first strut fracture was belatedly brought to the FDA's attention and explained as an "isolated incident" even though it was unexplained at the time of the application. *Id.* at 21. Further, Shiley made claims, based on unsubstantiated data, that reduced

heart complications would result from Shiley valve implants.[2] *Id.* at 22-24. Despite these deficiencies, the FDA approved the PMA on April 27, 1979, without a recorded vote. *Id.* at 22.

Between 1979 and 1983, the struts which hold the mechanical valves in place in 73 Shiley valves fractured, *id.* at 28, leading to the death of most of the implanted individuals. These fractures were the result of both the valve's design and poor manufacturing processes. In particular, the valves suffered from poor welding and poor quality control. *See id.* at 5-14; App. 461, 615-16, 623-25. During this period, Shiley sent a set of letters to doctors and to the FDA reassuring them that these incidents did not compromise the integrity, safety, or effectiveness of the device. Energy & Commerce Report at 14-17. Despite a redesign of the manufacturing process, continuing strut fractures forced Shiley to recall those valves which had not been implanted in 1980, 1982, and 1983. Because of continuing problems with valve failures, Shiley recalled its larger size valves and ceased production of those sizes in October 1985. Finally, on November 24, 1986, Shiley withdrew all its remaining valves from the market and ceased production of any heart valves. On March 21, 1990, Shiley asked the FDA to withdraw its Premarket Approval. To date, approximately 501 Shiley valves have fractured, resulting in 347 deaths. App. 691.

These events first affected Nina Michael in 1981. In that year, Michael was diagnosed with a congenital defect with her mitral heart valve, which controls of the flow of blood between the left atrium and the left ventricle. Because the defect was potentially fatal, Michael underwent surgery to have her natural heart valve replaced with the Shiley valve on November 24, 1982.

---

[2] Specifically, Shiley claimed a reduction in the rate of thromboembolism, the development of potentially dangerous blood clots at the valve's location. The FDA later determined that there was no improvement in the rates of thromboembolism with the new valve and that this information, if known at the time the PMA was filed, would likely have prevented FDA approval. App. 766-68.

The surgery was successful and the valve functioned properly. The valve implanted in Michael came with the following disclosure under the heading "Disclaimer of Warranties":

> Shiley warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether express, implied, written or oral.

App. 680.

In the late 1980s and early 1990s, Michael became aware of the strut fracture problem through media sources and her doctor. Research disclosed that her class of valves was among the Shiley valves with the highest rate of failure. It was estimated that there was a two percent chance per year that a catastrophic valve failure would occur in the Shiley valve implanted in Michael. These disclosures caused Michael significant anxiety, which resulted in sleeplessness and other emotional and physical symptoms.

After consultations with her physicians, Michael had the Shiley valve surgically removed and replaced with a different valve in June 1992. The surgeon visually examined her explanted valve and found no visible defects. The valve was later discarded.

In March 1993, Michael filed a complaint in the Philadelphia Court of Common Pleas, alleging state law claims of negligence, strict product liability, breach of implied warranties, breach of express warranties, and fraud. App. 10-29. Her complaint named Shiley Inc., the maker of the Shiley valve; Pfizer Inc., Shiley's corporate parent; and Hospital Products Group Inc., another corporate owner of Shiley. Shiley removed the case to the Eastern District of Pennsylvania on the basis of diversity jurisdiction. App. 31. On August 16, 1993, Shiley filed two summary judgment motions. One motion alleged that all claims except the express warranty claim were preempted. The second motion alleged that Michael had failed to raise a genuine issue of material fact to support her claims.

Through orders dated February 25, 1994, March 31, 1994, and April 7, 1994, the district court granted judgment on all the claims against Michael and in favor of Shiley. It granted judgment on the negligence, strict product liability, and implied warranty claims on both pre-emption and traditional Rule 56 grounds. *See* Fed.R.Civ.P. 56(c). It granted judgment on the express warranty claim for failure to raise a genuine issue of material fact. Finally, it granted judgment on the fraud claim solely because it was pre-empted.

Michael filed a timely notice of appeal.

II

We exercise plenary review of the district court's grant of summary judgment and apply the same test that the district court should have applied initially. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir.1976), *cert. denied*, 429 U.S. 1038, 97 S.Ct. 732, 50 L.Ed.2d 748 (1977). Thus, we will affirm only if Michael has failed to raise a genuine issue of material fact and Shiley is entitled to a judgment as a matter of law. *Id.* In examining the record, we give the nonmoving party the benefit of all reasonable inferences from the record. *Gray v. York Newspapers, Inc.*, 957 F.2d 1070, 1078 (3d Cir.1992). We exercise plenary review over the district court's pre-emption determination, as it is a question of law. *Travitz v. Northeast Dep't ILGWU Health & Welfare Fund*, 13 F.3d 704, 708 (3d Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 2165, 128 L.Ed.2d 888 (1994). We also exercise plenary review over the district court's application of state law. *Salve Regina College v. Russell*, 499 U.S. 225, 231, 111 S.Ct. 1217, 1221, 113 L.Ed.2d 190 (1991).

III.

A.

The parties' core dispute is whether, or to what extent, the MDA pre-empts Michael's state common law causes of action. Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the

Contrary notwithstanding." U.S. Const. art. VI, cl. 2. By virtue of this grant of federal power, Congress can through a sufficiently clear expression of its intent displace state law. *Cipollone v. Liggett Group, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992);[3] *CSX Transp. Inc. v. Easterwood*, ___ U.S. ___, ___, 113 S.Ct. 1732, 1737, 123 L.Ed.2d 387 (1993) ("[P]re-emption will not lie unless it is 'the clear and manifest purpose of Congress.' ") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947)). "In the interest of avoiding unintended encroachment on the authority of the States, however, a court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find pre-emption." *CSX Transp. Inc.*, ___ U.S. at ___, 113 S.Ct. at 1737.

Pre-emption may arise explicitly from the statute's language or implicitly from the statute's structure and purpose. *Morales v. Trans World Airlines, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2031, 2036, 119 L.Ed.2d 157 (1992). Nonetheless, "[w]hen Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of legislation." *Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2618 (quotations and citations omitted).

Because Shiley relies upon the express pre-emptive scope of 21 U.S.C. § 360k, our task is primarily one of statutory construction. *Id.* ___ U.S. at ___, 112 S.Ct. at 2621. We must give the language of § 360k "a fair but narrow reading" which

[3] We recognize that *Cipollone* was decided by a plurality of the Supreme Court. We are satisfied that the pre-emption discussion and holding represents the Court's current pre-emption analysis. *See, e.g., American Airlines, Inc. v. Wolens*, ___ U.S. ___, 115 S.Ct. 817, 130 L.Ed.2d 715 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.1994); *Weber v. Heaney*, 995 F.2d 872, 875 (8th Cir.1993); *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438, 1443 (10th Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 291, 126 L.Ed.2d 240 (1993).

will give effect to Congress' purpose without undermining "the strong presumption against pre-emption." *Id.*

Cipollone illustrates the manner in which we are to apply these doctrines. In *Cipollone*, the Supreme Court considered whether the Cigarette Labeling and Advertising Act of 1965 or the Public Health Cigarette Smoking Act of 1969 pre-empted Rose Cipollone's state common law causes of action for failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy claims. The Court concluded that the limited language of the 1965 act did not prevent a state claimant from recovering damages in a state common law cause of action not otherwise pre-empted. ___ U.S. at ___, 112 S.Ct. at 2619.

The Court turned to the broader pre-emption provision of the 1965 Act which stated "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of cigarettes. . . ." *Id.* ___ U.S. at ___, 112 S.Ct. at 2617. Applying a "fair but narrow" reading of this provision, the Court held that Cipollone could not maintain a failure to warn claim because the statute prevented states from requiring any warning beyond the federally mandated statement "CAUTION: CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH." *Id.* ___ U.S. at ___ - ___, 112 S.Ct. at 2621-22. In contrast, the Court concluded that Cipollone's express warranty and fraud claims could proceed. The contract claim was not "imposed under State law" and the fraud claim did not impose a requirement "with respect to the advertising or promotion of cigarettes." *Id.* ___ U.S. at ___-___, 112 S.Ct. at 2622-24.

B.

Statutory interpretation begins with an analysis of the statute's language. Section 360k(a) provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

This section pre-empts only state imposed requirements. Further, it pre-empts those requirements only when they differ from or add to a previously established FDA requirement and relate to the safety or efficacy of the regulated device. When a state law differs from or adds to a FDA requirement and when a state law relates to the safety or effectiveness of a device approved by the FDA, the state law is pre-empted. Conversely, when a state law neither imposes requirements nor differs from or adds to a FDA requirement nor relates to the safety or effectiveness of the device or to any other matter included in a FDA requirement, the state law is not pre-empted by § 360k.

C.

We first consider Michael's two threshold arguments: (1) that state common law does not impose "requirements" and (2) that the FDA imposed no "requirements" on Shiley. Either would prevent the MDA from pre-empting any of her claims.

An extended discussion of whether the state common law imposes requirements under the MDA is unnecessary.[4] We

---

[4] Michael points in particular to the FDA regulations which interpret § 360k. See 21 C.F.R. § 808.1. 21 C.F.R. § 808.1(d)(1) states: [Section 360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. Despite the reference in 21 C.F.R. § 808.1(d)(1) to laws of general applicability, we hold that the statutory language of § 360k preempts Michael's claims for breach of the implied warranties of merchantabil-

have already determined that the term "requirements" as used in § 360k encompasses state common law claims. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541-42 (3d Cir.), *cert. denied*, ___ U.S. ___, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994). In *Gile*, we followed the Supreme Court in its interpretation of the term "requirement" as used in § 5(b) of the Public Health Cigarette Smoking Act of 1969. There the Court "reject[ed Cipollone's] argument that the phrase 'requirement or prohibition' limits the 1969 Act's pre-emptive scope to positive enactments by legislatures and agencies." *Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2620.

D.

Michael next argues that, while we could normally conclude that the FDA had imposed requirements on a manufacturer, the unique facts of this case preclude such a determination. Michael's argument is based on failings in the Premarket Approval and oversight process which arose because Shiley's heart valve was among the first mechanical devices approved under the MDA. According to Michael, these failings kept the FDA from imposing any requirements on Shiley.

Michael claims that the lack of FDA requirements is proved by the absence of any specific regulations which govern heart valves as compared with the other medical devices. *Cf.* 21 C.F.R. §§ 813.1-813.170 (regulating the testing and manufacture of intraocular lenses); 21 C.F.R. §§ 870.1025-870.5925 (classifying and imposing requirements on various cardiovascular devices). To support this claim, Michael points to the FDA's statement that the MDA pre-empts state requirements only when the FDA "has established specific counterpart regulations or there are other specific requirements

---

ity and fitness as explained in section IV. A. *infra*. We express no view on the validity of § 808.1(d)(1) because Shiley disclaimed all implied warranties as it was entitled to do under the Code.

applicable to a particular device under the act. . . ." 21 C.F.R. § 808.1(d).

The absence of regulations relating specifically to heart valves is not dispositive as long as the Shiley valve was subject to "any requirement applicable under [the MDA] to the device." 21 U.S.C. § 360k(a)(1). While Shiley's premarket application may indeed have been flawed, there is ample evidence that the Shiley valve was subject to requirements under the MDA. First, it is clear that Shiley had to and did obtain a PMA prior to marketing the device. *See* 21 U.S.C. § 360e. After Premarket Approval was obtained, Shiley was subject to the labeling requirements of 21 C.F.R. §§ 801.1-801.16, which became effective February 13, 1976, and of 21 C.F.R. §§ 820.1-820.198, which defined the general "good manufacturing practices" ("GMP") required of medical device manufacturers after July 21, 1978. *See* 41 Fed.Reg. 6896 (1976); 43 Fed.Reg. 31508 (1978). The FDA had the power to force notification of a previously unknown risk under 21 U.S.C. § 360h(a)[5] and at least once threatened to use this

---

[5] 21 U.S.C. § 360h(a) reads in relevant part as follows:

(a) Notification

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk.

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturer, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk.

power. *See* app. 766-69. Even though these generally applicable regulations do not rise to the level of specificity present in the case of some other devices regulated by the FDA, we conclude that they present "specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d). They therefore constitute proper bases for pre-emption under § 360k.

IV

Having disposed of Michael's general allegations, we consider whether § 360k pre-empts the separate theories of recovery that Michael alleges. *See Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2621 (considering each of Cipollone's theories of recovery to determine if they are pre-empted). Because *Gile* has already determined that state law negligence and strict product liability claims are pre-empted under § 360k on account of the potential conflict with FDA labeling, design, and manufacturing requirements, we will not discuss those claims further than to restate that they are pre-empted. *See Gile*, 22 F.3d at 543-44.

A.

Breach of Implied Warranties—Pre-empted

Michael brings a claim for breach of the implied warranties of merchantability and fitness for a particular purpose. 13 Pa.C.S.A. §§ 2314, 2315. These Uniform Commercial Code causes of action meet the first requirement of pre-emption under § 360k; they are state imposed. They "arise by operation of law" in any transaction in goods in Pennsylvania. *Altronics of Bethlehem, Inc. v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir.1992).

The requirements imposed by §§ 2314 and 2315 also potentially differ from or exceed the FDA's requirements. To decide Michael's implied warranty claims, the jury would have to decide whether the Shiley valve was defective. *Id.*; *see also*

13 Pa.C.S.A. § 2314 (Goods must be "fit for the ordinary purpose for which such goods are used."). In Michael's case, this determination would require a finding that the heart valve's design was flawed, unreasonably dangerous, or poorly manufactured. *Id.*

This conclusion by necessity depends upon the accepted standards for the design and manufacture of products in the state of Pennsylvania. These standards may deviate from the FDA's determinations in the PMA process or from the FDA's "good manufacturing practices," which represent the agency's expert evaluation regarding the design and production of the Shiley valve. Section 360k does not permit this conflict. *Accord King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993).

B.

Express Warranty Based on Shiley's Label—Not Pre-empted

Michael also brought an express warranty claim based on Shiley's statement on its packaging that it "warrants that reasonable care has been used in the manufacture of this device." App. 680.

Before we address this issue, we must consider, as a threshold issue, whether the district court ruled that this claim was pre-empted. The district court's February 25, 1994 order granted Shiley's motion for partial summary judgment based on pre-emption. Shiley's motion had sought the entry of summary judgment on Michael's claims of negligence, strict product liability, breach of implied warranties, and fraud claims, but not on Michael's breach of express warranty claim. App. 48. However, in ruling on Shiley' motion, the district court stated, "[w]e have held that the MDA has wholly pre-empted plaintiff's state law claims against defendants." App. 1362. On appeal, Shiley has argued that we can reach the question of pre-emption because the district court granted summary

judgment on Michael's express warranty claim for failure to raise a genuine issue of material fact and we can affirm on any appropriate ground. Shiley's Br. at 28. Because "[t]he prevailing party may, of course, assert in a reviewing court any ground in support of his judgment, whether or not that ground was relied upon or even considered by the trial court," we will address that issue. *Dandridge v. Williams*, 397 U.S. 471, 475 n. 6, 90 S.Ct. 1153, 1156 n. 6, 25 L.Ed.2d 491 (1970).

Section 360k only pre-empts requirements which the state "establish[es]" or "continue[s] in force." The focus of § 360k is on preventing the States from imposing on medical device manufacturers normative policy choices which conflict with FDA requirements. *See Gile*, 22 F.3d at 546. This focus is consistent with the limited purpose for which Congress displaced the states' coordinate regulatory role—to permit efficient and effective FDA regulation of medical devices. The FDA itself has recognized the MDA's limited focus by interpreting § 360k to pre-empt only state requirements "having the force and effect of law," a term normally reserved for binding standards of conduct that operate irrespective of private agreement. 21 C.F.R. § 808.1(d).

1.

Express warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. *See* 13 Penn.Cons.Stat.Ann. § 2313. Implied warranties, on the other hand, "arise by operation of [state] law." *Altronics of Bethlehem v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir.1992). The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties.[6]

---

[6] The conceptual difficulty with determining whether, to what extent, and for what purposes contractual obligations arise by virtue of state action, on the one hand, or the autonomous actions of the parties, on

The underlying foundation of contract law is the objectively manifested intentions of the parties. E. Allan Farnsworth, *Contracts* §§ 1.1-1.3 (2d ed. 1990). Shiley, in the representation which appears on the Shiley valve label, clearly manifested an intent to be bound by its one unequivocal promise and to disclaim any other implied warranties. Shiley represented:

> Shiley warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether express, implied, written or oral.

App. 680.

2.

The Supreme Court has twice recognized this same distinction between state-imposed and state-enforced common law remedies. In *American Airlines, Inc. v. Wolens*, ___ U.S. ___, 115 S.Ct. 817, 130 L.Ed.2d 715 (1995), the Court held that the Airline Deregulation Act of 1978, 49 U.S.C. § 1305(a)(1), did not preempt Wolen's common law contract claims, writing

> We do not read the ADA's preemption clause, however, to shelter airlines from suits alleging no violation of state-imposed obligations, but seeking recovery solely for the airline's alleged breach of its own, self-imposed

---

the other, has been addressed time and again in the literature on the common law. *See, e.g.*, Jay M. Feinman & Peter Gabel, *Contract Law as Ideology in The Politics of Law* 373, 378 (David Kairys ed. 1990); Charles Fried, *Contract as Promise* 7-27 (1981). Ultimately, contractual obligations result from the confluence of state authority and private actions. While the "binding force" of a properly executed contract derives from state authority, the content of the commitment is determined (absent mandatory or impermissible terms) by the parties themselves. In this way, contractual obligations differ fundamentally from state imposed regulatory requirements, such as the FDA requirement that medical devices meet certain design parameters. Both the content and the effect of these regulations flow from governmental authority.

> undertakings. As persuasively argued by the United States, terms and conditions airlines offer and passengers accept are privately ordered obligations "and thus do not amount to a state's enact[ment] or enforce[ment] [of] any law rule, regulation, standard, or other provision having the force and effect of law' within the meaning of § 1305(a)(1)." Brief for the United States as Amicus Curiae 9. . . . A remedy confined to a contract's terms simply holds the parties to their agreements—in this instance to business judgments an airline made public about its rates and services.

___ U.S. at ___, 115 S.Ct. at 824.

Previously, in *Cipollone*, the Court concluded that § 5(b) of the Public Health Cigarette Smoking Act of 1969 did not pre-empt state contract law claims.

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirements" imposed by an express warranty claim are not "imposed under State law," but rather imposed *by the warrantor*. . . . In short, a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement . . . *imposed under State law*" within the meaning of § 5(b).

Cipollone, ___ U.S. at ___, 112 S.Ct. at 2622 (emphasis in original).

Moreover, our conclusion complies with the Supreme Court's admonition that courts should be "reluctant" to find pre-emption when "interpreting a federal statute pertaining to a subject traditionally governed by state law." *CSX Trans. Inc. v. Easterwood*, ___ U.S. ___, ___, 113 S.Ct. 1732, 1737, 123 L.Ed.2d 387 (1993). This is especially true here where Congress remained silent as to whether the MDA pre-empted common law contract claims. The elimination of those claims might result in the elimination of all legal remedies to the purchaser. "It is difficult to believe that Congress would,

without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S.Ct. 615, 623, 78 L.Ed.2d 443 (1984).

In this case, Congress has not only remained silent as to whether it intended to prevent states from enforcing the contractual representations of medical device manufacturers, it gave indications in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation. Section 360h(d) defines the effect that a manufacturer's compliance with an FDA notification, reimbursement, or recall order should have:

> Compliance with an order issued under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

While this provision does not delineate the scope of the state law remedies that remain after the MDA's passage, it contemplates that injured persons will be able to pursue a category of claims for economic loss under some circumstances. We conclude that express warranty claims are included in that category.

3.

Shiley points to previous cases that have concluded that the same or similar federal regulatory schemes do pre-empt contract claims because the contract claims conflict with the FDA's supervision over medical device labeling. *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir.1993)[7];

---

[7] In *Worm v. Cyanamid Co.*, the Fourth Circuit decided that the pre-emption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b), pre-empted the plaintiff's contract claims because the claims were based on instructions for use found on the product label which were required and approved by EPA regulations. 5 F.3d at 749. Because the Fourth Circuit found that these instruc-

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993)[8]; *Kemp v. Pfizer, Inc.*, 851 F.Supp. 269 (E.D.Mich.1994).[9] These courts have held that pre-emption was appropriate because the state law causes of action arose from representations made by manufacturers on labels approved by the FDA or EPA. The courts reasoned that because these labels were approved by the relevant regulatory authority, they could not give rise to voluntary obligations undertaken by agreement and so would conflict with federal regulation.

If for no other reason, *Worm* is distinguishable from this case because it deals with a separate statutory scheme. *Worm* dealt with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), not the MDA. Second, the plaintiff in *Worm* complained that Cyanamid had provided improper instructions for the use of the insecticide on its label, giving rise to a contract claim. 5 F.3d at 748-49. Michael is not challenging the instructions for the use or the implantation of the Shiley valve. Rather she seeks to enforce the company's explicit warranty which guarantees the product.

King and *Kemp* are less easily distinguished. The court in *King* did not indicate the type of language or warning upon which the plaintiff relied in the case before it and so we cannot know if it is distinguishable from Michael's claims. *Kemp* dealt with the same product and the same warranty as is at issue in the present case.

---

tions were mandated by the Environmental Protection Agency, the court concluded that the express warranty claims were pre-empted. *Id.*

[8] *In King v. Collagen Corp.*, the First Circuit concluded that § 360k pre-empted King's express warranty claims because those claims arose from the language on the packaging approved by the FDA. 983 F.2d at 1135. "Allowing appellant's express warranty claims effectively would impose additional or different requirements on Zyderm's labeling and packaging." *Id.*

[9] *In Kemp v. Pfizer, Inc.*, the district court followed the reasoning of *King* and *Worm* to hold that § 360k pre-empted a contract claim against Pfizer, Hospital Products Group, and Shiley, the defendants in this case.

Neither *King* nor *Kemp* are binding on this court and we conclude that the concern expressed in those cases, that warranty obligations would arise from and therefore be in conflict with statements that are required on a regulated label, does not make preemption appropriate. First, the fact that third parties dictate or define the terms of a contract does not undermine the doctrine that contractual duties arise from the mutual assent of parties to agreed upon language. For example, organizations that receive government grants to operate social programs frequently agree to include specified language in agreements with contractors and beneficiaries. *See, e.g.*, 24 C.F.R. § 85.36(i) (1994) (mandating the inclusion of specified terms in contracts between Housing and Urban Development grant recipients and local parties); *Ayers v. Philadelphia Housing Authority*, 908 F.2d 1184 (3d Cir.1990) (discussing HUD mandates for contracts between the local housing authority and the local authority's tenants/purchasers). Government contractors must agree to specified compensation and wage terms in their contracts with employees who work on the government projects. *See, e.g.*, 40 U.S.C. §§ 328-29, 333; 41 U.S.C. § 351; 29 C.F.R. §§ 4.1 to 4.51; 29 C.F.R. § 5.5. Courts do not thereby conclude that these requirements cause the immediate parties' contractual relationships to arise from the federal mandate. Regardless of the economic and legal pressures that dictate the final terms, the contract still results from the parties' mutual agreement to those terms.

Further, *King* and *Kemp* did not adequately consider the extent to which Shiley's label was ultimately a product of its voluntary actions. The FDA does not devise a label of its own making. Rather, Shiley submitted its proposed label to the FDA, which label was then reviewed with the company. Shiley itself drafted the initial language of the label. If Shiley disagreed with FDA recommendations, it could have engaged in negotiation over what statement was proper or, if it did not wish to be bound by the required statement, it could have chosen not to market its device. Despite indications in *King* and *Kemp* to the contrary, we believe that Shiley participated

actively and meaningfully in the FDA regulatory process that resulted in the label which we review here.

4.

Even if this were not the case, the enforcement of an express warranty that arises from approved packaging does not establish a requirement that "is different from, or in addition to, . . . any requirement applicable under this chapter to the device." 21 U.S.C. § 360k. Through her express warranty claim, Michael seeks to enforce the very language which the FDA approved on the Shiley valve label. Given the clarity with which that language speaks of warranties, neither the FDA, Shiley, nor Michael could have mistaken this language as creating anything other than an explicit contractual obligation. Thus, it is the FDA's own requirement that Michael would have the state enforce.

If any person, other than Shiley, "established" the warranty, it was the FDA, not the state. Because the obligations imposed arise directly from the FDA's own approved language, the resulting liability does not differ from or add to FDA regulation. Rather it supports the FDA's approval regulation by giving it effect.

Michael's contract claim is not a product of state action; hence, it is not state imposed—the *sine qua non* of preemption under § 360k. Michael's express warranty claim is not preempted and can be prosecuted.

V

Michael also brought fraud claims relying on two theories of recovery. First, she alleges that Shiley fraudulently misled the FDA to her eventual, but foreseeable, detriment. Second, she alleges that Shiley's unregulated promotional and advertising materials fraudulently misrepresented that the Shiley valve was safe and would produce fewer complications than other valves when the company knew that these claims were

not supportable. We consider whether § 360k preempts each of these claims.

A.

Fraud on the FDA—Pre-empted

Michael produced substantial evidence that Shiley misled the FDA with false or misleading information when it applied for Premarket Approval. She claims that these fraudulent submissions led to the FDA's approval of the Shiley valve and thus led eventually to the necessity of removing the heart valve implanted in her. Alternatively, she argues that these fraudulent submissions estop Shiley from claiming that the MDA preempts its common law claims. Because of the conflict with the FDA's own efforts to monitor and control its PMA application process, we conclude that Michael's claims for Shiley's knowing misrepresentation to the FDA, even if provable, are pre-empted.

A state law cause of action for fraud is a state imposed requirement. By means of its recognized cause of action in fraud, the Commonwealth of Pennsylvania imposes a duty on anyone who sells products. That duty requires the seller to avoid any material misrepresentation that could induce purchasers to buy its product. *See Moser v. DeSetta*, 527 Pa. 157, 589 A.2d 679, 682 (1991).

Michael seeks to use this general prohibition on deception to encourage the district court to review the PMA application Shiley submitted to the FDA. This inquiry could ultimately require that a court determine whether the information Shiley submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA.

Section 360k does not permit such a searching state inquiry into the inner workings of FDA procedures. Congress allo-

cated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. *See* 21 U.S.C. § 360e (creating the PMA requirement). Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices. Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA. "[W]here the FDA was authorized to render the expert decision . . . , it, and not some jury or judge, is best suited to determine the factual issues and what their effect could have been on its original conclusions." *King*, 983 F.2d at 1140 (Aldrich & Campbell, J.J. concurring). Under the MDA, states have no authority to police Shiley's compliance with the FDA's procedures. If Shiley knowingly misled the FDA in its PMA application, it is for the FDA to remedy that situation using the authority Congress gave it in the MDA.

Further, permitting a fraud claim based on false representations to the FDA would conflict with our precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, ___ U.S. ___, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994). Plaintiffs cannot circumvent this bar by characterizing their cause as a claim for state law fraud.

Nor can Michael revive the pre-empted fraud claim by characterizing it as a defense to pre-emption. Michael argues that, though her fraud claim might be pre-empted, her allegations of Shiley's fraud in obtaining its PMA, if proven, should deprive Shiley of the defense of pre-emption. In essence, Michael argues that we should not permit Shiley to invoke the cloak of federal pre-emption when it obtained that cloak through the fraudulent manipulation of the regulatory process.

While we do not condone misconduct by medical device manufacturers, we cannot agree with Michael's theory. If a medical device manufacturer's claim that the MDA pre-empts

a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry which we have just demonstrated is forbidden. Only the timing, and not the inquiry itself, would differ from a claim for fraud on the FDA. This argument thus presents not less, but greater interference with the FDA's decisions. An attempt to reexamine the FDA's approval under state law standards, however pleaded, is pre-empted by § 360k.

B.

Fraud Based on Shiley's Advertisements—Not Pre-empted

Michael's second fraud claim differs from the first in that it does not rely on conduct which was directly regulated by the FDA. Michael alleges that Shiley sent cardiac surgeons and cardiologists a series of letters and other promotional materials which knowingly misrepresented the extent of the valve fracture problem and knowingly overstated the reduction in serious side effects achieved by the Shiley valve. *See FDA and the Medical Device Industry, Hearing Before the House Committee on Energy and Commerce*, 101st Cong., 2d Sess. 15-21 (1990) (providing samples of these letters); App. 393-95. Michael alleges that the company's misinformation resulted in the eventual harm she suffered when her valve was explanted.

1.

Having already concluded that state law fraud claims create state-imposed requirements and, when combined with other § 360k elements, are thus pre-empted, *see* section V.A. *supra*, we need only consider the other elements of pre-emption under § 360k.[10] The FDA had not imposed specific

[10] The Supreme Court recently held that the Airline Deregulation Act of 1978 ("ADA") preempted the enforcement of a state consumer fraud statute, the Illinois Consumer Fraud Act, 815 Ill.Comp.Stat.

requirements related to advertising and promotion of the Shiley valve. Accordingly, we find that, as applied to Michael's circumstances, a state law fraud claim based on Shiley's advertising and promotional activities does not impose a requirement that "is different from, or in addition to" a FDA requirement and "which relates to the safety or effectiveness of the device or to any matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k.

Unlike Michael's strict liability claims which are based on a duty to produce safe products, Michael's fraud claims are based "on a more general obligation—the duty not to deceive." *Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2624. Thus, Michael's fraud claim does not relate to the safety or effectiveness of the Shiley valve. Michael argues that because this duty to avoid deceit does not "relate to the safety or effectiveness of the [Shiley valve]," her claims are not pre-empted.

She relies on *Cipollone* for this argument. In *Cipollone*, the Supreme Court concluded that Cipollone's fraud claims against cigarette manufacturers were only pre-empted to the extent they sought to impose additional warnings on the cigarette packages. The Court permitted Cipollone's fraud claims for "claims based on allegedly false statements of material fact made in advertisements." *Id.* ___ U.S. at ___, 112 S.Ct. at 2623-24. The Court made this distinction because Cipollone's second claim based on "the duty not to deceive" did not conflict with federal requirements of § 5 of the Public Health Cigarette Smoking Act of 1969 which only

---

§ 505/2. *American Airlines, Inc. v. Wolens*, ___ U.S. ___, ___ - ___, 115 S.Ct. 817, 82225, 130 L.Ed.2d 715 (1995). In *Wolens*, the Supreme Court held that state consumer fraud statute was a state imposed law. *Id.* The Court then found that the Illinois state statute met the other element of pre-emption under the ADA, that is, the statute "relate[d] to [airline] rates, routes, or services." 49 U.S.C. § 1305(a)(1). Here, of course, the other requirements which dictate preemption under § 360k of the MDA differ from the requirements which dictate pre-emption under § 1305(a)(2) of the ADA. As stated in text, we conclude that Michael's common law fraud claim is not pre-empted by § 360k.

preempts state law claims "based on smoking and health." *Id.* ___ U.S. at ___, 112 S.Ct. at 2624.

If § 360k also limited its pre-emptive scope to state requirements "which relate[ ] to the safety or effectiveness of the device," Michael's argument might be compelling, but § 360k is not so limited. It extends as well to state requirements "which relate[ ] . . . to any matter included in a requirement applicable to the device under this chapter." Thus, we must determine not only whether Michael's fraud claim relates to "safety and effectiveness"—which we hold it does not—but also whether it relates to any other FDA requirement.

2.

This latter inquiry turns on whether the FDA imposed any requirements on Shiley's efforts to promote its heart valve. The record reflects that it did not. Shiley prepared and sent the letters to doctors which tout the valve's reliability and superiority as compared to competitors' valves without the FDA's approval. App. 393-94. The FDA, at that time, was not supervising medical device manufacturers' efforts to promote their devices outside of a limited category of "restricted devices" defined by the MDA and not relevant to this appeal. Only in the last few years has the FDA actively sought to control the promotional representations which device makers make to the medical community. Sandra J.P. Dennis, *Promotion of Devices: An Extension of FDA Drug Regulation or a New Frontier*, 48 Food & Drug L.J. 87 (1993). We note, however, that this on-going extension of the FDA's authority has been criticized as exceeding the FDA's statutory mandate. *See id*; Jeffrey N. Gibbs, *Medical Device Promotional Activities and Private Litigation*, 47 Food & Drug L.J. 295 (1992).

To be sure, the FDA did regulate the information Shiley placed on its labels. As required by the MDA, Shiley submitted its labels to the FDA and the FDA approved them. (*See* section IV. B. *supra*). A deviation from the content of the label approved by the FDA violates the MDA. 21 C.F.R.

§ 814.39(a)(2). Nonetheless, there is a substantial difference between supervising label content and supervising advertising.

Mindful that the Supreme Court has observed in a slightly different context that "Congress offered no sign that it wished to insulate . . . manufacturers from longstanding rules governing fraud," *Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2624, we conclude that Michael's second theory of fraud is not precluded by § 360k and is thus not pre-empted.

Our conclusion does not conflict with First Circuit's determination in *King* that § 360k pre-empted King's fraud claim. 983 F.2d at 1136. King's fraud claim arose from the absence of warnings on the label of the medical device. *Id.* Because the FDA regulates the labeling of medical devices, King's claims were pre-empted. Michael's theory does not depend upon Shiley's representations on its labeling. Unlike in *King* where the court determined that the plaintiff's fraud claim was, "at bottom, a failure to warn claim," *id.*, and thus pre-empted by the MDA, Michael's fraud claim is, at bottom, a fraudulent promotion claim. As such, it is not pre-empted.

VI

Summary Judgment—Sufficient Evidence

Although the district court granted summary judgment on the majority of Michael's claims because it believed they were pre-empted, it also analyzed the claims using the traditional standard for summary judgment. We have concluded that Michael's express warranty claim and her fraud claim are not pre-empted. However, our holding in this regard does not address the district court's ruling that Michael had failed to present sufficient evidence to proceed to trial. We address that issue here and hold that, on this record, it was error to grant summary judgment for Shiley.

A.

Our consideration of Michael's contract claims originates with an examination of the contract. The label attached to the heart valve, which was implanted in Michael, included the statement "Shiley warrants that reasonable care has been used in the manufacture of this device." App. 680. This language clearly created an express warranty with regard to the manner in which Shiley manufactured its heart valves. Shiley does not deny that the sale created a valid contract with an express warranty. *See* 13 Pa.C.S.A. § 2313. Rather Shiley contends that it never breached the warranty because there is no proof that the valve implanted in Michael was defective.

We agree that there is no evidence in the record that Michael's valve was defective. That does not, however, defeat Michael's cause of action. Shiley's warranty does not simply warrant that the valve which was implanted in Michael was defect-free. The language is less specific, warranting instead that "reasonable care has been taken in the manufacture of this device." App. 680.

We are satisfied that the representation made by the language on this label reaches beyond the valve explanted from Michael to encompass the manufacture of Shiley valves generally. While most consumers of most products have little reason to seek assurances in a contract that any device, other than the product purchased by them, is safe and effective, heart valve purchasers, as perhaps other purchasers of implanted devices, have salient and compelling reasons to seek such assurances.

Shiley's customers rely on Shiley's mechanical heart valves in a manner that differs entirely from the normal buyer's reliance on a consumer product. The Shiley valve sustains customer's lives. Malfunction will result in serious harm, or most likely, death. In this context, the purchaser has reason to demand a very high degree of assurance that the implanted product presents no substantial risk that it will fail. The existence of a significant risk that the device will fail makes the

product unsuitable for its purpose. Therefore, a patient-purchaser has every reason to seek, and Shiley has every reason to give, assurances that reasonable care has been taken in the production of such life sustaining devices generally. It is only such a warranty that can alleviate concerns that an implanted medical device will fail without warning.

Shiley's warranty afforded its patient purchasers those assurances. Michael proceeded with her implant operation with a justifiable belief that the valve implanted in her heart would not fracture or fail due to deficiencies in the manufacturing process. Because any latent defect in an implanted device may be undetectable after it has entered medical supply channels, the representations made by the manufacturer, which here form the basis of Shiley's warranty, requires an examination, not just of the specific heart valve implanted in Michael, but rather of Shiley's valve production generally.

The evidence in the record suggests that Shiley did not exercise due care in the fabrication of the Bjork-Shiley valve. A number of Shiley valves failed as a result of welding cracks that were not prevented or eliminated at Shiley's factories. Michael also submitted to the court the findings of a House Committee report on the manufacture of Shiley's valves. That report stated that Shiley trained welders inadequately, repaired valves which had previously been deemed not repairable by inspectors, and masked cracked welds to pass quality inspections. She also produced a letter to Shiley from a medical researcher, stating that "[y]our statement re. strut fracture that I just received only tells me that your manufacturing procedure is not acceptable." App. 461. Former welders stated in affidavits that Shiley trained welders poorly and told welders to force badly welded valves past quality control personnel. App 615-16, App. 623-25. This record could amply support a jury determination that Shiley did not exercise reasonable care in the manufacture of its heart valves.

Michael has also shown that Shiley's alleged manufacturing breaches caused her damage. Shiley's failure to manufacture its heart valves using proper care resulted in a risk that any of its heart valves could fail. Indeed, the weak or improper strut construction has resulted in over 500 documented strut failures. Nor, as we have pointed out, could it be determined without explantation whether the valve implanted in Michael suffered from any of the same defects that affected other valves. Accordingly, Michael's doctors concluded that it was reasonable to explant her Shiley valve and replace it surgically. App. 499-501, 526-29; *see also* app. 471 (Shiley document sent to doctors noting an investigative article which recommended replacement of heart valves in young patients). Michael understandably took the advice of her medical advisors. The cost, inconvenience, risk, and pain of the surgery to explant and replace the valve occurred because of Shiley's alleged general manufacturing deficiencies which led to Shiley's alleged breach of its warranty of reasonable care.

Contrary to Shiley's arguments, our conclusion does not conflict with our recent decision *Angus v. Shiley, Inc.*, 989 F.2d 142 (3d Cir.1993).[11] In *Angus*, we concluded that a recipient of a Shiley valve could not recover for intentional infliction of emotional distress and a failure to warn claim where the implanted valve had neither failed *nor been explanted*. *Id.* at 147 & n. 5. Angus had failed to allege that the valve implanted in Angus was defective. *Id.* In the absence of a valve failure or explantation surgery, she could not maintain a product liability action. *Id.* In footnote 5, we explicitly held open the question of whether relief would be appropriate following surgery to explant the valve. *Id.* at 147 n. 5.

---

[11] Shiley claims we had earlier determined that a plaintiff whose valve had not failed could not recover for emotional distress on any product liability theory in *Brinkman v. Shiley, Inc.*, 732 F.Supp. 33 (M.D.Pa.), *aff'd without opinion*, 902 F.2d 1558 (3d Cir.1989); *see* Shiley Brief at 41. We, of course, are not bound by an unpublished disposition of our court. *See* Third Circuit Internal Operating Procedures § 5.8. Moreover, the plaintiff in *Brinkman*, unlike the plaintiff here, had not undergone explantation surgery.

Unlike the plaintiff in *Angus*, Michael has suffered a tangible injury on account of the risks, pain, and emotional trauma associated with explantation of the Shiley valve. Michael's case presents the issue left open in *Angus*—what relief may be accorded for physical and emotional trauma occasioned by the need for actual explantation surgery. We conclude that, under the terms of Shiley's express warranty, sufficient evidence has been shown by Michael to withstand entry of summary judgment for Shiley. Our conclusion is consistent with Pennsylvania's rule that emotional harm may be recovered when it accompanies a physical injury. *Houston v. Texaco, Inc.*, 371 Pa.Super. 399, 538 A.2d 502, 504 (1988).

B.

Finally, we consider whether Michael produced sufficient evidence to proceed to trial on her fraud claim.[12] In Pennsylvania, the elements of fraud are: (1) a material misrepresentation of fact, (2) which is false, and (3) made with knowledge of its falsity, (4) which is intended to induce the receiver to act, and (5) upon which a party justifiably relies. *Mellon Bank Corp. v. First Union Real Estate*, 951 F.2d 1399, 1409 (3d Cir.1991).

> It is well established that fraud consists of anything calculated to deceive, whether by single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or by innuendo, by

---

[12] The somewhat confusing nature of the district court's orders makes it uncertain that the district court determined that Michael did not raise a genuine issue of material fact on her fraud claim. While the court granted a judgment on her fraud claim on the belief that it was preempted, a conclusion which we now reverse, the court granted Shiley's motion for summary judgment for failure to produce sufficient evidence on all claims "except plaintiffs fraud claim." Nonetheless, because we exercise the same review as the district court did in the first instance, we will consider the merits of Shiley's motion, particularly since the two district court orders appear on their face to conflict with one another.

> speech or silence, word of mouth, or look or gesture. We have held that "fraud is composed of a misrepresentation fraudulently uttered with the intent to induce the action undertaken in reliance upon it, to the damage of its victim." The concealment of a material fact can amount to a culpable misrepresentation no less than does an intentional false statement.

Moser v. DeSetta, 527 Pa. 157, 589 A.2d 679, 682 (1991) (quoting *Thomas v. Seaman*, 451 Pa. 347, 304 A.2d 134, 137 (1973)) (other citations omitted).

In support of her claim, Michael points to two sources of fraudulent information: (1) letters written by Shiley to doctors between 1978 and 1983 which attempt to minimize the significance of the prior valve fractures and (2) advertisements and other promotional materials which emphasize a reduction in complications with the Shiley valve that never materialized.

Michael claims that Shiley's representations to doctors in letters, which accompanied its recalls and which Shiley otherwise disseminated to boost the Shiley valve's image following the disclosure of the outlet strut fractures, misrepresented the extent of the strut fracture problem. These letters state that some fractures had occurred but purportedly withheld information on the actual number of strut fractures known to Shiley. Further, the letters asserted that the Shiley valve's original design and the then current manufacturing practices confirm the structural integrity of the Shiley valve.

In contrast to Shiley's reports, the record discloses that Shiley had ample reasons to believe both the heart valve's design and the manufacturing process rendered the heart valve unsafe. Just a month prior to Shiley's distribution of a set of letters to doctors in May 1982, Dr. Bjork, one of the original designers of the Shiley valve, wrote Shiley, "You're circling around with other solutions is probably a waste of time. At this stage, welding will not be acceptable any more [sic]. . . . Your statement re. strut fractures that I just received only tells me that your manufacturing procedure is

not acceptable. You have provided me with absolutely no facts and truthworthy [sic] data for the future." App. 461.

In a prior letter to Dr. Bjork, Shiley had written, "We would prefer that you did not publish the data relative to strut fractures. We expect a few more and until the problem has been corrected, we do not feel comfortable." App. 548. This disclosure contrasts with Shiley's assurances in the letters to doctors that new fractures were very unlikely to occur.

Moreover, Michael has produced affidavits and deposition testimony from employees who worked for Shiley in the late 1970s and early 1980s that state that Shiley supervisors and management ordered them to reweld valves which could not pass inspection, to polish or cover defects in outlet strut welds, and to rework previously scrapped valves in an attempt to hide any defects in the outlet strut welds. App. 555-57, 613-17, 625-29, 635-36. These manufacturing practices likely undermined the structural integrity of the valves and thereby rendered Shiley's representations false.

Michael has also produced samples of advertisements, which Shiley placed in medical journals that circulate to cardiac surgeons, claiming a fifty percent reduction in complications with the Shiley valve over prior valves. App. 678. In prior testimony, Dr. Bjork disagreed that this claim fully represented the scientific findings. App. 812. By 1984, the FDA, through independent investigation, concluded that scientific tests could not confirm these reductions. App. 766. In fact, the FDA determined that the Shiley valve's design "d[id] not result in meaningful differences in thromboembolic complications in clinical experience. . . . After nearly eight years of clinical use, there is no statistically significant difference between [the Shiley valve and its predecessor] when thromboembolic complication rates are compared." *Id.*

This record reveals a sufficient pattern of affirmative statements that are contrary to the true information known to Shiley, which, when combined with the withholding of material information as to the integrity and properties of the Shiley valve, is more than sufficient to permit a jury to conclude

that Shiley intentionally misrepresented the Shiley valve's performance and the importance of the strut fractures.

Having adduced evidence of the first three elements of a cause of action sounding in fraud, we turn to a consideration of the remaining two elements: inducement and justifiable reliance. We conclude that Shiley had ample reason to expect that its advertisements and letters, although directed to physicians, would induce action by heart patients to accept Shiley's implants on the basis of their physicians' recommendations. We also conclude that the patients' reliance on these recommendations was justifiable.

Pennsylvania has held that "the persons or class of persons whom [a fraudulent declarant] intends or has reason to expect to act or refrain from action in reliance upon the misrepresentation" may sue in fraud for the damage which results from the declarant's fraudulent statement. *Woodward v. Dietrich*, 378 Pa.Super. 111, 548 A.2d 301, 309, 315 (1988) (quoting Restatement (Second) of Torts § 531 (1976)).

In *Woodward*, the Pennsylvania Superior Court held that a subsequent transferee of a home could sue the prior owner's plumbing contractor, when the plumber had fraudulently misrepresented to the prior owner that his work met the relevant municipal codes. The plumber fraudulently concealed an improper link to the city's sewer system after being hired by the Dietrichs, the former owners of the house, to bring the house up to code. After the Dietrichs sold the home to the Woodwards, the sewer line backed up into the house's basement. The Woodwards brought a cause of action sounding in fraud against the plumber.

The Pennsylvania Superior Court adopted the rule of the Restatement (Second) of Torts § 531 (1976), which reads:

> One who makes a fraudulent misrepresentation is subject to liability to the persons or class of persons whom he intends or has reason to expect to act or refrain from action in reliance upon the misrepresentation, for pecuniary loss suffered by them through their justifiable

> reliance in the type of transaction in which he intends or has reason to expect their conduct to be influenced.

This provision extends liability beyond those to whom the declarant directs his fraudulent misrepresentation to those whom the declarant has special reason to anticipate will be induced to act. *Woodward*, 548 A.2d at 313, 315. As comment "e" of the Restatement makes clear, the declarant need not know the identity of the eventual plaintiff if the plaintiff is a member of a class of persons whom the declarant has reason to expect will act in reliance upon his fraud. Restatement (Second) of Torts § 531 comment e (1976) ("The maker may have reason to expect that his misrepresentation will reach any of a class of persons, although he does not know the identity of the person whom it will reach or indeed of any individual in the class."); *Woodward*, 548 A.2d at 309 n. 9.

After adopting this standard, the court found that the plumber had reason to expect that any subsequent purchaser, such as the Woodwards, would rely on his fraudulent statement that the sewer connection was acceptable, and thus, the court permitted the Woodwards to proceed with their fraud action.[13]

The Superior Court's decision mirrors § 533 of the Restatement (Second) of Torts. Section 533 makes a declarant liable when the declarant "has reason to expect that [the misrepre-

---

[13] More recently, the Pennsylvania Superior Court relied upon its opinion in *Woodward* to decide that plaintiffs need not have been in privity with a product manufacturer to bring a claim under Pennsylvania's consumer fraud statute, the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa.Stat.Ann. § 209-9.2(a). *Valley Forge Towers South Condominium v. Ron-IKE Foam Insulators, Inc.*, 393 Pa.Super. 339, 574 A.2d 641, 64647 (1990), *aff'd without opinion*, 529 Pa. 512, 605 A.2d 798 (1992). As a result, a condominium association could sue their roofing contractor's supplier for the supplier's unlawful business practices despite the fact that the association never purchased materials from the supplier. Rather it had only received a warranty from the supplier. "[A]s the materials were intended to become part of a fixture to realty, [the supplier] knew or should have known that its warranty would be relied upon by [the condominium association] covered by the roof it warranted." *Id.* 574 A.2d at 646.

sentation's] terms will be repeated or its substance communicated to the other, and that [the misrepresentation] will influence his conduct in the transaction or type of transaction involved." *See Ostano Commerzanstalt v. Telewide Systems, Inc.*, 794 F.2d 763, 766 (2d Cir.1986) (holding licensor liable to sublicensee for representations made to licensee with reason to expect that they would influence sublicensee's behavior). As with § 531, the comments to § 533 make it clear that the declarant (here, Shiley) need not be able to identify the party (here, Michael) who eventually relies if the party (here, Michael) who relies is a member of a class of people that the declarant (here, Shiley) would expect to rely on the representation. Restatement (Second) of Torts § 533 comment g (1976).

Michael fits within the rule of *Woodward* and Restatement § 533. Shiley had ample reason to expect that the patients and eventual recipients of the Shiley valve implants would be affected by the information it published and distributed to doctors. Indeed, that was Shiley's intent. Shiley had to anticipate that its letters and advertisements would lead doctors to recommend, and the physician's patients to choose, the Shiley valve. As § 533 makes clear, the fact that Shiley initially made its representations to Michael's doctors, rather than directly to Michael, does not undermine Michael's claim.

By the same token, Michael's doctors were justified in relying on the medical claims Shiley provided in its promotional materials to determine the proper course of treatment for Michael.[14] Shiley held a tremendous advantage over the doctors in its knowledge of the facts surrounding the strut fractures and the scientific literature on thromboembolism.

---

[14] Both her doctors testified that they received letters from Shiley regarding the Shiley valve. App. 495, 524. While they did not retain those letters, it is reasonable to assume, given Shiley's nationwide distribution of the letters, that these letters include the communications discussed above. Both doctors stated that they read standard cardiac journals in which Shiley's advertisements and claims appeared in order to stay current with developments in the field of cardiology and cardiac surgery. App. 500, 535.

The doctors were justified in relying on Shiley to restate honestly the facts and findings pertaining to the valves which Shiley produced. *See Aaron Ferer & Sons, Ltd. v. Chase Manhattan Bank*, 731 F.2d 112, 123 (2d Cir. 1984) (where "one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of the mistaken information," the second party can justifiably rely on the first party's representations); *Daughtrey v. Ashe*, 243 Va. 73, 413 S.E.2d 336, 338 (1992) ("[I]f one who has superior knowledge makes a statement about the goods sold and does not qualify the statement as his opinion, the statement will be treated as a statement of fact."); Restatement (Second) of Torts § 542(a) & comment f (1965).

The information provided by Shiley was intended to affect a doctor's choice of a heart valve for Michael. Shiley distributed its literature containing heart valve information for that very purpose—to encourage doctors to continue implanting the Shiley valve. The record, read in the light most favorable to Michael, suggests that the doctors, who advised Michael, relied on Shiley's disclosures. Accordingly, Shiley's letters and promotional materials likely affected the choice to implant the Shiley valve in Michael.

We conclude that Michael has produced sufficient evidence to raise a genuine issue of fact on her claim of fraud and we will reverse the district court's February 25, 1994 orders of summary judgment on that claim.

VII

Having considered the record and the arguments of the parties, we will affirm the district court's grant of summary judgment on Michael's claims of negligence (both manufacturing and design), strict product liability, and breach of implied warranties—all of which we hold are pre-empted by 21 U.S.C. § 360k. (*See* section IV.A. *supra*). We also hold that Michael's complaint to the extent it relies on fraud perpetrated by Shiley on the FDA is pre-empted. (*See* section V.A. *supra*.)

We will reverse the district court's February 25, 1994 order granting summary judgment to Shiley on Michael's breach of express warranty claim (*see* section IV.B. & VI.A. *supra*) and her fraud claim insofar as she proceeds on the basis of Shiley's representations in its advertising and promotional materials. (*See* section V.B. & VI.B. *supra*).

We will remand the case to the district court for further proceedings consistent with the foregoing opinion.

UNITED STATES DISTRICT COURT
E.D. PENNSYLVANIA

No. CIV. A. 93-1729
Feb. 25, 1994

NINA MICHAEL

—v.—

SHILEY, INC. *et al.*

MEMORANDUM

DALZELL.

Plaintiff Nina Michael commenced this action because of her concerns about a Bjork-Shiley heart valve prosthesis that was implanted in her in 1982 and was removed ten years later because of her fears about its safety. She sued defendants Shiley, Inc., Hospital Products Group, Inc. and Pfizer, Inc. in the Philadelphia Court of Common Pleas. Pursuant to 28 U.S.C. § 1446, defendants removed the action to this Court.[1]

Ms. Michael's complaint alleges negligence, intentional infliction of emotional distress (Count I), strict products liability (Count II), breach of express warranty, breach of implied warranty of merchantability, breach of warranty of fitness for a particular purpose (Count III), and fraud (Count IV), as well as *respondeat superior* liability, alter ego liability, and civil conspiracy (Count V).

---

[1] Because of the diverse citizenship of the parties to this complaint, as well as of the evident financial dimensions to this controversy, removal was proper pursuant to 28 U.S.C. § 1441(a).

Now before us are defendants' motion for summary judgment as a matter of law on all Counts, and defendants' motion for partial summary judgment on Counts I, II, IV and the breach of implied warranty claim alleged in Ms. Michael's complaint, based on federal preemption by virtue of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq. After consideration of all of the parties' voluminous submissions[2], we will grant defendants motions.

I. Factual Background

On November 24, 1982, Nina Michael's cardiologist performed open heart surgery on her and replaced her failing natural mitral heart valve[3] with a Bjork-Shiley 60 degree Convex-Concave Mitral Heart Valve Prosthesis, size 29 mm, serial number 29MBRC16390 ("Shiley heart valve"). Defendants manufactured Ms. Michael's Shiley heart valve in August of 1981. Plaintiff's Memorandum in Opposition to Defendants' Motion for Summary Judgment Dismissing Complaint ("Plaintiff's Memorandum"), p. 2; *id.* at Exhibit 22.

Through articles and television programs such as *20/20*, Nina Michael learned of incidents of alleged failure or malfunction of Shiley heart valves similar to the one implanted in her. Ms. Michael claims that after hearing reports that Shiley heart valves suffered from design and manufacturing defects and that malfunctions of the Shiley heart valve had lead to fatalities, she "sustained severe emotional distress and fear of a catastrophic malfunction of her [Shiley] valve." Plaintiff's Complaint, ¶ 9

On June 10, 1992, after consulting with her doctors, Ms. Michael underwent surgery to "explant" and replace her Shi-

---

[2] Among the advocacy submitted for our consideration was defendants' letter in reply to plaintiff's surreply.

[3] Ms. Michael had an implant when she was only 38 because she suffered from mitral insufficiency, which "is when the valve leaks, it allows blood to regurgitate or leak back into the chamber." Deposition of Dr. James D. Sink at p. 19.

ley valve with another manufacturer's heart valve. Until the time it was removed, Ms. Michael's heart valve was functioning properly and there was no indication that it had malfunctioned or would have malfunctioned in the future. Dr. James D. Sink, during the explantation surgery, visually inspected the Shiley valve and observed no evidence of defects or malfunctions. Dr. Sink sent the removed valve to the Presbyterian Medical Center pathology department, where it was eventually discarded. Sink Dep., p. 66-68.

Ms. Michael commenced this action on March 9, 1993 to recover damages for economic losses, including the cost of the original heart valve, the cost of the explantation surgery, pain and suffering for physical injury and emotional distress, and emotional distress as caused by defendants' alleged fraud. She also seeks punitive damages.

It is undisputed that the United States Food and Drug Administration ("FDA") had given premarket approval to the Shiley heart valve on April 27, 1979. Defendants' Motion for Partial Summary Judgment, Exhibit A. The valve was approved as a Class III medical device and, therefore, subject to the Medical Device Amendments. Before receiving premarket approval, the FDA required Shiley to submit proposed labeling information, safety testing data, and descriptions of methods and materials used to manufacture the device. *See* 21 U.S.C. § 360e(c)(1). Once it received premarket approval, Shiley was required to maintain records and make reports to the FDA, which at all times had regulatory authority over the product. The FDA always retained the power to withdraw its approval and remove the device from the market. 21 U.S.C. §§ 360h, 360i.

In May of 1983, because of strut fractures, Shiley voluntarily recalled its heart valves, including the type implanted in Ms. Michael. Plaintiff's Memorandum, Exhibit 2, p. 11; *see also id.* at Exhibit 22. By November of 1986, Shiley voluntarily withdrew the remaining valves from the market and stopped producing them.

On March 21, 1990, Shiley's Vice-President and Medical Director wrote to the FDA to report that:

> Shiley will not at any time reintroduce this product into commerce in the U.S. or overseas. Therefore we request that the PMA [premarket approval] be withdrawn.

This letter also added,

> As we have discussed, notwithstanding the withdrawal of the PMA, Shiley will continue to cooperate closely with FDA and remain subject to the FDA regulations as though the PMA remained open, including filing MDR reports and quarterly valve statistics, sharing information and research on noninvasive predictive testing and fracture mechanics, and coordinating communications with the medical community.

Plaintiff's Answer, Exhibit 37.

The FDA's Center for Devices and Radiological Health, responded with a March 30, 1990 letter (Plaintiff's Answer, Exhibit 38). The Center advised that it would treat Shiley's request as constituting the voluntary withdrawal of the premarket approval of the Shiley heart valve.

II. Legal Standard for Summary Judgment

As noted earlier, defendants have submitted both a motion for partial summary judgment based on preemption under the Medical Device Amendments, which we shall address in part III, and a motion for summary judgment as a matter of law, which we shall address in part IV. Though the facts necessary to resolve these motions are largely undisputed, we first rehearse the familiar standards for summary judgment.

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue is "genuine" only if there is a sufficient evidentiary basis on which a reasonable jury could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). A factual dispute is "material" only if it might

affect the outcome of the suit under governing law, *id.* at 248, and all inferences must be drawn, and all doubts resolved, in favor of the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962); *Gans v. Mundy*, 762 F.2d 338, 341 (3d Cir.), *cert. denied*, 474 U.S. 1010 (1985).

On a motion for summary judgment, the moving party bears the initial burden of identifying for the Court those portions of the record that it believes demonstrate the absence of dispute as to any material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). To defeat summary judgment, the nonmoving party "may not rest upon the mere allegations or denials of [its] pleading, but [its] response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e).

Specifically, the non-moving party must produce evidence such that a reasonable juror could find for that party. *Anderson*, 477 U.S. at 248. When considering how a reasonable juror would rule, the court should apply the substantive evidentiary standard—in this instance, a preponderance of the evidence—that the fact-finder would be required to use at trial. *Id.* at 252. A mere scintilla of evidence will not require the court to send the question to the fact-finder. *Id.* at 251 (citing *Improvement Co. v. Munson*, 14 Wall. 442, 448 (1872)).

III. Preemption Under the Medical Device Amendments of 1976

Defendants' arguments lead us first to consider whether, and to what extent, Ms. Michael's state claims are preempted by the FDA's regulation of the Shiley heart valve under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* ("MDA"). Because of the Supremacy Clause of the U.S. Constitution,[4]

[4] The Supremacy Clause provides: This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the

state laws are subordinated to explicit federal laws and regulations.

We must first decide whether there is preemption and, second, the scope of that preemption. Section 360k(a) of the MDA is the pertinent provision in the statute, and it provides:

> **(a) General rule**
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The canons of preemption analysis are well-established. When construing a federal statute and determining whether it preempts state laws and regulations, ultimately it is Congressional intent that prevails and preemption will only occur if it is clearly Congress' purpose to preempt state law. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947). Congress may expressly evidence its intent to preempt state law through the explicit language of a statute, as it has done here, or it may express its intent implicitly by adopting a comprehensive statute. *Id.* Implied preemption also occurs when state law would stand as an obstacle to accomplish Congress' purposes or when state law actually conflicts with federal law where it would be impossible to comply with both. *Fidelity Federal Sav. & Loan Asso. v. De La Cuesta*, 458 U.S. 141, 152-53, 102 S.Ct. 3014, 3022 (1982) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. at 230, 67 S.Ct. at

---

Constitution or Laws of any State to the Contrary notwithstanding. U.S. Const., art. VI.

1152). Congressional preemption " 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.' " *Id.* (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309 (1977)).

In addition, "[a] federal agency exerting its regulatory mandate may preempt state regulation if that agency is 'acting within the scope of its congressionally delegated authority.' " *Bravman v. Baxter Healthcare Corp.*, No. 89 Civ. 3444, 1994 WL 21131, at *5 (S.D.N.Y. Jan. 24, 1994) (quoting *Louisiana Pub. Service Comm'n v. F.C.C.*, 476 U.S. 355, 369 (1986)).

Although neither the Supreme Court nor our Court of Appeals has addressed this issue under the MDA, we do not lack guideposts. The Supreme Court considered the issue of tort preemption most recently in *Cipollone v. Liggett Group, Inc.*, ___ U.S. ___, 112 S.Ct. 2608 (1992), and three other Courts of Appeals have addressed the specific issue of the preemptive scope of § 360k(a) of the MDA. *See Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, ___U.S. ___, 114 S.Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, ___ U.S. ___, 113 S.Ct. 327 (1992).

When one reads the ordinary English of § 360k, there seems little question that Congress has expressly evidenced its intent to preempt state regulation by explicitly providing that no state may establish any requirement "which is different from, or in addition to" the requirements of the MDA or which relate "to the safety or effectiveness of the device" over which the FDA has plenary jurisdiction. The First Circuit in *King* gave § 360k this natural construction, and held the statute to be an express preemption provision rather than an implied preemption; it also held that "the fact that Congress included it in the MDA implies that matters beyond its reach are not preempted." *King*, 983 F.2d at 1134.[5] The

[5] Judge Aldrich and Judge Campbell, in what they style their concurring opinion (but what seems to us to be rather clearly the opinion of

Fifth and Seventh Circuits came to the same conclusion in *Stamps* and *Slater*, 984 F.2d at 1423-1424[6], 961 F.2d at 1334, respectively.

We cannot improve on Judge Aldrich's analysis in *King*, 983 F.2d at 1138-1139, and thus adopt it to hold that § 360k(a) represents "maximum protection and express preemption, leaving no need to seek implications." *Id.* at 1139.

We now turn to consider the scope of the preemption. We begin by considering the meaning of the first use of the word "requirement" in § 360k(a). Ms. Michael argues that the statute's references to "requirement" does not include court decisions because *Cipollone* found that "requirement" referred only to " 'standards and regulations' adopted as positive enactments within a state's purposeful regulatory scheme." Plaintiff's Response, p. 19. We agree with defendants that Ms. Michael misinterprets *Cipollone*.

In *Cipollone*, the Court considered whether § 5(b) of the Federal Cigarette Labeling and Advertising Act (the "1965 Act"), 15 U.S.C. §§ 1331-1340, preempted state law tort claims. A plurality of Justices Stevens, White, O'Connor and The Chief Justice held that the express preemption language prohibiting any "statement relating to smoking and health" in the 1965 Act applied only to "positive enactments" (i.e., statutes) and not to common law damages actions, but found that the express preemption provision of the Public Health Cigarette Smoking Act of 1969 amendments, 15 U.S.C. §§ 1331-1340 (the "1969 Act"), encompassed common law rules as well as state statutes because it barred not only statements, "but rather 'requirement[s] or prohibition[s] . . . imposed under State law.' " *Cipollone v. Liggett Group, Inc.*,

---

the court), found that Congress clearly intended the FDA requirements to be "total maximum protection," i.e., a ceiling and not a floor from which states can impose stricter standards. *King*, concurring opinion at 1138.

[6] The Fifth Circuit rejected plaintiff's argument "that the MDA forms only the floor of regulation; the states are free to construct a regulatory ceiling." 984 F.2d at 1424.

112 S.Ct. at 2619. Because of the broad reading the plurality gave to the words "requirement or prohibition", the statute was held to preempt state law claims, and in particular certain of plaintiff's failure to warn and fraudulent misrepresentation claims arising out of cigarette advertising and promotion. *Id.* at 2623-2624.

Though Justice Scalia, writing for himself and Justice Thomas, took "issue with the plurality . . . on its application of these general principles to the present case", 112 S.Ct. at 2634, they agreed with the general principle that the 1969 Act's preemption language "embraces state common law". *Id.* Thus, six Justices in *Cipollone* agree as to this fundamental reach of federal preemption into state common law when the preempting statute calls for the supersession of any state "requirement."

We must also consider the meaning of the second use of the word "requirement" in subsections (1) and (2) of § 360k(a), i.e., whether it embraces FDA regulations. The Supreme Court in *Chevron United States, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843, 104 S.Ct. 2778, 2781-2782 (1984), found that an agency's interpretation of a statute that the agency administers is controlling so long as it does not conflict with Congress' intent. 21 C.F.R. § 808.1(d) provides that state requirements are preempted only when the FDA has established specific regulations or requirements applicable to the particular device.[7] The only regulation specifically pertaining to heart valves appears at 21 C.F.R. § 870.3925.[8] *Bravman*, 1994 WL 21131, at *10, *see Kemp v.*

---

[7] This regulation covers three pages of 21 C.F.R., pp. 60-62, and will not be reproduced here because of its length.

[8] This regulation provides in full:

"Replacement heart valve.

(a) *Identification.* A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(*footnote continued*)

Pfizer, Inc., 835 F.Supp. at 1020. Because § 870.3925 only identifies replacement heart valves, we must determine whether there are other requirements pertaining to the valves within the meaning of § 360k(a) that would preempt state law claims.

In the Seventh Circuit's decision in *Slater, supra*, the plaintiff brought state tort claims of negligence, strict liability, and breach of implied warranty against the manufacturers of an experimental intraocular lens.[9] Judge Posner wrote for the Court that there were specific FDA regulations which governed the "procedures for determining whether the experimental design is safe and effective", and therefore held that § 360k(a) required preemption of the state tort claims even in the absence of an explicit FDA regulation governing the intraocular lens. *Slater*, 961 F.2d at 1333.

The First and Fifth Circuits in *King* and *Stamps, supra*, considered whether state tort law claims involving a Class III medical device called Zyderm were preempted by § 360k of the MDA. The plaintiffs in those cases allegedly contracted an autoimmune disease as a result of using the defendant's product. The plaintiff in *King*, for example, sued for strict liability, breach of warranty of merchantability, negligence, misrepresentation, failure to warn and fraud on the FDA. As noted earlier, both *Stamps* and *King* found that the MDA preempted all of these state law claims.

"(b) *Classification.* Class III (premarket approval).

"(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 9, 1987 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has on or before December 9, 1987 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution."

9 Intraocular lenses are plastic lenses implanted in a patient who has had cataract removal surgery. *Slater*, 961 F.2d at 1332.

The First Circuit in *King* found that because the manufacturer had to undergo the premarket approval process, the FDA had established specific "requirements" within the meaning of § 360k of the MDA and § 808.1(d) of the FDA's regulations. *King*, 983 F.2d at 1132. The court, in holding that plaintiff's express warranty claims were preempted by the MDA, made this persuasive contrast with *Cipollone*:

> In *Cipollone*, the statute required cigarette manufacturers to include a brief health warning in their advertisements; this warning did not affect cigarette advertisements in any other way. The manufacturers were free to make any claims they wished, including express warranties. Here, however, the MDA has imposed much more extensive regulation upon class III device manufacturers. The FDA retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims. This high level of control contrasts with the low level of control in *Cipollone*, and ensures that manufacturers will not be held liable for packaging and labeling imposed by the FDA.

983 F.2d at 1135.

Stamps came to a similar conclusion. The Fifth Circuit held that the FDA's premarket approval process and regulatory structure "completely preempted" plaintiff's state law claims, which included inadequate labeling, defective design and defective manufacture counts. *Stamps*, 984 F.2d at 1425. Also contrasting *Cipollone*, the Fifth Circuit held that, "Simply put, Texas tort liability, following *Cipollone*, would constitute a requirement either different from, or in addition to, a requirement—the class III PMA process—that the MDA has made applicable to" the devices under the FDA's jurisdiction. 984 F.2d at 1421.

In addition to the Courts of Appeals, two district courts have also held that the MDA expansively preempts state law for Class III medical devices. *See Kemp v. Pfizer, Inc.*, 835

F.Supp. 1015, 1020 (E.D.Mich.1993) (plaintiff's tort claims including negligence, failure to warn, strict liability, breach of implied warranty of merchantability and fraud were preempted because decedent's heart valve had undergone the premarket approval process and was subject to FDA regulations); *Bravman v. Baxter Healthcare Corp.*, 1994 WL 21131 (S.D.N.Y. January 24, 1994) ("state tort remedies—such as Bravman's duty to warn claim—would be preempted when the FDA chose to approve the Valve as a Class III device and its proposed labeling").

We are aware of no peculiarity in Pennsylvania law[10] that would lead ~~us~~ to diverge from the reasoning set forth in *Stamps* and *King* and applied in *Kemp* and *Bravman*. We find these cases to be persuasive and, accordingly, we also find that the premarket approval process and postapproval regulations are "requirements" within the meaning of § 360k(a) that preempt Pennsylvania law claims involving the Shiley heart valves.

We are aware, however, that the Supreme Court in *Cipollone* found that "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. at 2618; *see also id.* at 2625 (Blackmun, J., concurring). The Seventh Circuit in *Slater* also explained that the MDA's preemption was not a "blanket preemption" as broad as the preemption in ERISA which supersedes all state law. *Slater*, 961 F.2d at 1334.

To give proper regard to *Cipollone*'s teachings about federal-state comity, we must apply § 360k(a) to each of Ms. Michael's common claims law to be sure that the breadth of the MDA's reach preempts those claims.[11]

---

[10] Because our jurisdiction is founded upon diversity of citizenship, we must apply the substantive law of the forum state, *Erie R.R. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817 (1938), and the parties do not appear to dispute the application of Pennsylvania law.

[11] Plaintiff argues that because defendants voluntarily withdrew their premarket approval, the FDA no longer has jurisdiction over defendants' product and therefore, their claims should not be preempted.

We must in particular consider whether Pennsylvania's laws, including its common law, establish any requirements which differ from or add to the requirements of the MDA applicable to the Shiley heart valves, or which relate "to the safety or effectiveness of the" Shiley heart valves or to some other matter included in the premarket approval requirements applicable to those devices. *See Stamps v. Collagen Corporation*, 984 F.2d at 1422.

As we have already discussed, *see* note 8 *supra* and accompanying text, there is one FDA regulation specifically regarding heart valves, but that regulation merely identifies a specific device under the FDA's jurisdiction. We will therefore focus on whether Pennsylvania state laws "relate to" the premarket approval requirements or the post-approval regulations. As will be seen, we are greatly aided in this enterprise by following the First Circuit's analysis in *King*.

(a) Negligence, Strict Products Liability

Plaintiff claims that defendants were negligent in manufacturing the Shiley heart valve and that this negligence caused plaintiff intense anxiety, which led her to seek surgery to "explant" and replace her properly functioning heart valve. Plaintiff's strict liability claim asserts that the heart valve was defective and that defendants' device was unreasonably dangerous.

We note at the threshold that the MDA, at 21 U.S.C. § 360j, sets forth manufacturing requirements. Additionally, § 360c(a)(1)(C) requires that the FDA ensure that reasonable safety is used in the production of Class III devices.

Because plaintiff's claims relate to a product which was manufactured and sold during the premarket approval process and when the premarket approval was in effect, if we were to find there was no preemption, we would be allowing states retroactively to establish requirements different from or in addition to the requirements of the MDA. Given the broad jurisdiction of the FDA to enforce the Food Drug and Cosmetic Act, *see* 21 U.S.C. § 371 and 21 C.F.R. part 5.10 (1992), *see also Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 829, 106 S.Ct. 3229, 3243 (1986), we find plaintiff's argument unpersuasive.

If Ms. Michael were to proceed on her strict liability and negligence claims, a jury would be called upon to rule that defendants should have redesigned the product, used different manufacturing methods, altered their sales and marketing techniques or be subject to tort liability. In short, the evidence plaintiff would adduce in support of these claims would necessarily "relate to"[12] the proper procedures for manufacturing defendants' product and to the safety and effectiveness of the heart valve. *See King v. Collagen Corp.*, 983 F.2d at 1136, *Kemp v. Pfizer, Inc.*, 835 F.Supp. at 1021. As noted, § 360k(a) of the MDA explicitly preempts any state law which "relates to the safety and effectiveness" of a Class III device.

We therefore find that plaintiff's negligence and strict products liability claims must be preempted.

(b) Failure to Warn

Ms. Michael's complaint also alleges that defendants failed to warn of the "dangers and defects in and associated with using the [Shiley heart valve]." Plaintiff's Complaint, ¶ 13(e). Sections 352 and 360 of the MDA restrict packaging and labeling of devices, and § 360h of the MDA provides for notifications relating to public health risks and for recall of devices. A finding of a failure to warn would "challenge the adequacy of [defendants'] FDA-regulated packaging and labeling" because it would "impose a requirement on [defendants] to change [their] packaging or labeling." *King*, 983 F.2d at 1136.

We therefore hold that Pennsylvania's failure to warn causes of action are preempted because they would compel different or additional packaging and labelling requirements to those the MDA authorizes the FDA to specify.

---

[12] The recent decision of *Morales v. Trans World Airlines, Inc.*, ___ U.S. ___, 112 S.Ct. 2031 (1992), gave a broad reading to the words "relates to" when construing another express preemption statute. The Court referred to a definition from *Black's Law Dictionary:* "to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with." *Morales*, 112 S.Ct. at 2037.

(c) Breach of Implied Warranty

Because the MDA imposes regulations over packaging and labeling, the FDA has " 'largely displac[ed] the ability of manufacturers to make additional claims.' " *Kemp v. Pfizer, Inc.*, 835 F.Supp. at 1021 (quoting *King v. Collagen Corp.*, 983 F.2d at 1135). An implied warranty of merchantability is a requirement "that arises exclusively from the operation of state contract law" and is preempted because "[o]therwise, it would impose a requirement additional to those imposed under the MDA." *King v. Collagen Corp.*, 983 F.2d at 1135-1136; *see also Kemp v. Pfizer, Inc.*, 835 F.Supp. at 1021.

We entirely agree with the reasoning described in *King* and *Kemp*, and hold that Ms. Michael's claim of a breach of implied warranty is preempted by the MDA.

(d) Fraud

Plaintiff claims that fraud was committed not only on her, but also on her doctors and on the FDA. This is, as Judge Aldrich observed in *King*, "[a] more troublesome issue", *King*, 983 F.2d at 1139.

In *King*, the First Circuit noted that a fraud claim is, "at bottom, a failure to warn claim." *King v. Collagen Corp.*, 983 F.2d at 1136. As we have just discussed, a failure to warn claim is preempted. Plaintiff's fraud claim suggests that defendants should have changed their packaging, labeling or reporting to the medical profession or to the FDA. Since the MDA has detailed requirements covering those areas, § 360k of the MDA necessarily preempts plaintiff's fraud claim.

Judge Aldrich (and Judge Campbell) in his separate opinion in *King* came to the same conclusion, but for a slightly different reason:

> To prove fraud, plaintiff must show causality. Surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual

> issues and what their effect would have been on its original conclusions.

983 F.2d at 1140.

Ms. Michael nevertheless asserts that § 360k did not preempt her claim for "fraud causing disparagement". In essence she asserts that defendants created a special relationship to her when they induced her to put her life at the mercy of defendants' heart valve. Because of this special relationship, Ms. Michael avers that defendants owed her a special duty to refrain from "act[ing] in a way which would disparage the integrity and reputation for reliability of themselves and their heart valves" knowing that such actions would "cause Plaintiff to become extremely anxious and to suffer emotionally." Plaintiff's Response to Defendants' Motion for Partial Summary Judgment Based on Federal Preemption ("Plaintiff's Response"), p. 48.

In advancing this argument, Ms. Michael seeks solace in *Cipollone*'s holding that § 5(b) of the 1965 Act only preempted "state law obligations 'with respect to the advertising or promotion' of cigarettes." *Cipollone*, 112 S.Ct. at 2623. It will be recalled that the Supreme Court in *Cipollone* found that the plaintiff's fraudulent misrepresentation claim was not preempted because it was based on a state law duty not to deceive, and was not predicated on a duty based on smoking and health.

Similar to the argument made in *Cipollone*, Ms. Michael claims that her fraud claim is not preempted because it is based on a duty other than that which the statute preempted. Ms. Michael argues that her fraud claim would not affect the device and is based on "[d]efendants' over-all behavior of marketing a heart valve product upon which it knew [p]laintiff's life would become dependent." Plaintiff's Response, p. 48. The MDA, however, unlike the 1965 or 1969 Acts, is, as the First Circuit noted in *King*, 983 F.2d at 1135, far more comprehensive, and pervasively regulates defendants' marketing behavior through its standards and regulation of label-

ing, packaging and manufacturing. Therefore, the MDA displaces plaintiff's "fraud causing disparagement" claim.

Ms. Michael also alleges fraud was committed on the FDA, and therefore seeks in effect to act as a private attorney general on the agency's behalf. We find no warrant for allowing Ms. Michael to serve as the FDA's champion. The district court in *Kemp* found that a fraud on the FDA theory would be preempted because the fraud was committed "during and after the premarket approval of the C/C valve." *Kemp*, 835 F.Supp. at 1021. It further found that it would be the FDA's province and not the court's to determine which medical devices are safe and effective. *Id.*

We find *Kemp*'s conclusion compelled not only by § 360k of the MDA, but also because we believe it would be institutionally imprudent for courts to decide whether accurate representations had been made to the FDA. The FDA is an independent, expert agency with ample powers to set internal rules and regulations. It, not a judge or jury, is best situated to determine what reports submitted to it are reliable and when a device should receive premarket authority.

We are fortified in this conclusion by the Supreme Court's observation in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 93 S.Ct. 2488 (1973), where the Court was addressing whether a defendant's drug should be considered a "new drug" within the meaning of the FDCA, 21 U.S.C. § 301 *et seq.*, and whether it should be exempted from the statute. The Court admonished that "[t]hreshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand." *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. at 654, 93 S.Ct. at 2494.

In the last analysis, Congress has decided that the FDA is in the best position to conclude whether it has been defrauded. As the court in *Kemp* noted, if defendants did commit the fraudulent actions that Ms. Michael alleges, they would be subject to criminal prosecution. *See* 21 U.S.C. § 333. Plaintiff's services on behalf of the FDA are therefore not required.

IV. Summary Judgment on Substantive Claims

To the extent that any doubt exists about the comprehensiveness of the MDA's preemption of plaintiff's state law claims, and considering the merits of the claims we found preempted, we would alternatively grant summary judgment on the following claims.

(a) Breach of Express and Implied Warranties

In her complaint, Ms. Michael claims that Shiley made warranties that her heart valve "was safe and effective for its intended use, fit for its intended purposes, adequately and properly designed, tested and manufactured, not defective, and/or of merchantable quality." Plaintiffs Complaint, ¶ 24. In support of this assertion, plaintiff submitted a copy of Shiley's "Care and Handling Instructions" for its heart valve which includes a "Disclaimer of Warranties" which provides, in relevant part: "Shiley warrants that reasonable care has been used in the manufacture of *this device*." Plaintiff's Memorandum, Exhibit 24 (emphasis added).

Ms. Michael alleges a breach of warranty under the Uniform Commercial Code. If not preempted by the MDA, 13 Pa.Con.Stat.Ann. § 2313 would govern the express warranty made in this case. It provides, in relevant part:

> **(a) General rule.**—Express warranties by the seller are created as follows:
>
> (1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

Ms. Michael cannot recover under this provision, however, because she failed to submit any evidence to show that defen-

dants did not use reasonable care in the manufacture of her heart valve. In fact, Ms. Michael agrees that her heart valve had been working properly until she had it explanted and replaced. Because there was no evidence of malfunction—indeed, Dr. Sink testified he saw nothing wrong with the device when he inspected it after ten years' use—the heart valve conformed to the express warranty.[13]

Addressing Ms. Michael's argument that there was a breach of implied warranty of merchantability[14] or a breach of warranty of fitness for a particular purpose[15], we find that there

---

13 Although plaintiff contends that defendants may not have used reasonable care in the manufacture of other heart valves and, thus, breached warranties made to other purchasers, we are aware of no Pennsylvania law which would extend these warranties to Ms. Michael who sustained neither personal injury nor damage to property as a result of such a breach. *See Spagnol Enterprises, Inc. v. Digital Equipment Corp.*, 390 Pa.Super. 372, 380, 568 A.2d 948, 952 (1989).

14 13 Pa.Con.Stat.Ann. § 2314 provides:

> "**(a) Sale by merchant.**—Unless excluded or modified (section 2316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. . . .
>
> ". . .
>
> "**(b) Merchantability standards for goods.**—Goods to be merchantable must be at least such as: (1) pass without objection in the trade under the contract description; (2) in the case of fungible goods, are of fair average quality within the description; (3) are fit for the ordinary purposes for which such goods are used; (4) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; (5) are adequately contained, packaged, and labeled as the agreement may require; and (6) conform to the promises or affirmations of fact made on the container or label if any."

15 13 Pa.Con.Stat.Ann. § 2315 provides:

> "Where the seller at the time of contracting has reason to know: (1) any particular purpose for which the goods are required; and (2) that the buyer is relying on the skill or judgment of the seller to select or furnish suitable goods; there is unless excluded or modified under section 2316 (relating to

is no evidence that her heart valve malfunctioned or was working improperly and, therefore, there is no evidence that (a) the product was not fit for its particular purpose or (b) was not merchantable. In addition, the warranty at issue in this case includes a disclaimer excluding an implied warranty of merchantability and of fitness, which is valid because it conforms to the requirements of 13 Pa.Con.Stat.Ann. § 2316.

We will therefore grant summary judgment in favor of defendants on the breach of warranty claims.

(b) Section 402A, and Intentional Infliction of Emotional Distress

Plaintiff's complaint alleges that defendants are strictly liable for the defects in the product and for failure to warn of potential dangers and defects. Plaintiff's Complaint, ¶ 18. Plaintiff also claims that defendants' conduct has caused her to experience extreme emotional distress. *Id* at ¶ 14.

(1) No Defect in the Product

In order to prove strict liability[16], the plaintiff must show that "the product was defective, and . . . that the defect was a proximate cause of the plaintiff s injuries." *Berkebile v. Brantly Helicopter Corp*, 462 Pa. 83, 93-94, 337 A.2d 893, 898 (1975). Strict liability applies to injuries caused by manufacturing defects, and also to injuries caused by a design defect. *Lewis v. Coffing Hoist Div., Duff-Norton Co.*, 515 Pa. 334, 528 A.2d 590 (1987).

Ms. Michael does not dispute that there was no evidence of a defect in her particular heart valve. In fact, her surgeon testified that when he visually inspected the valve during the removal procedure "it appeared to be put in properly and it appeared to be working properly." Sink Dep., p. 67-68. To the

---

exclusion or modification of warranties) an implied warranty that the goods shall be fit for such purpose."

[16] The Pennsylvania Supreme Court adopted the strict products liability doctrine set forth in section 402 of the Restatement (Second) of Torts in *Webb v. Zern*, 422 Pa. 424, 220 A.2d 853 (1966).

question, "[i]n sum, did you observe any evidence of any kind of any form of malfunction of the Shiley valve?", he replied, "I did not." *Id.* In addition, Dr. Sink agreed that it would be "fair to say" that Ms. Michael's heart valve "performed properly and sustained her life" from the time it was implanted to the time it was removed. *Id.* Plaintiff therefore suffered no physical injury as a result of her heart valve malfunctioning. The suffering she doubtless experienced stemmed from her decision to have an elective operation which she felt she needed as a result of her anxiety that her Shiley heart valve might fracture.

Our Court of Appeals in *Angus v. Shiley, Inc.*, 989 F.2d 142 (3d Cir. 1993), recently addressed claims similar to those of Ms. Michael's. Although the plaintiff in that case, Ms. Angus, did not have her heart valve removed, the case is instructive because of its other, very similar facts. In *Angus*, plaintiff was implanted with a Bjork-Shiley prosthesis heart valve. Ms. Angus alleged that defendant Shiley, Inc. "deliberately manufactured the valves notwithstanding its knowledge of the strut fracture problem, failed to warn Angus of the problem, misrepresented the product, and concealed its knowledge of the problem." *Id.* at 143. Like Ms. Michael, the plaintiff in *Angus* alleged that after watching *20/20* and becoming aware of alleged problems with the Shiley heart valves, she experienced severe emotional distress from fear of sudden death or of permanent injury.

Ms. Michael, like the plaintiff in *Angus*, does not allege a defect with the valve implanted in her, which our Court of Appeals stated is "a prerequisite to liability in a products liability action." *Angus*, 989 F.2d at 147. Plaintiff does not cite, nor are we aware of, any authority from the Pennsylvania Supreme Court which would allow recovery on these facts that *Angus* found to be meritless. We will therefore grant defendant's motion for summary judgment with regard to strict liability for a product defect.[17]

---

[17] Ms. Michael concedes that "a 402A claim of strict products liability is an incorrect description of her right to recovery." Plaintiff's Memorandum, p. 1 note 1.

(2) Absence of Warnings

In order to prove her alternative failure to warn claim, Ms. Michael must show that the lack of warning made the product defective or unreasonably dangerous, and that the lack of warning was the proximate cause of her injury. *Berkebile v. Brantly Helicopter Corp.*, 462 Pa. 83, 337 A.2d 893 (1975).

The plaintiff in *Angus*, like Ms. Michael, asserted just such a failure to warn claim. In disposing of Ms. Angus's claim, the Court of Appeals stated that "this allegation at least at this time cannot be the basis for liability because the valve has not failed and the lack of warning did not cause Angus somehow to misuse the valve or was not otherwise the proximate cause of injury to Angus." *Id.* at 148.

Similarly, Ms. Michael's valve did not fail, and there is no evidence that the lack of warning caused Ms. Michael to misuse the product or that it was the proximate cause of any injury to her. Therefore, we will grant defendants' motion for summary judgment on this claim.

(3) Intentional Infliction of Emotional Distress

Ms. Michael claims that defendants' conduct (such as allegedly using faulty manufacturing procedures and engaging in deceitful behavior) was "so extreme and outrageous" that it would permit recovery under an intentional infliction of emotional distress cause of action She claims that she experienced extreme emotional distress "from the fear of sudden death, as well as the need for open heart surgery to remove the unreliable valve," Plaintiff's Memorandum, p. 36, and that to recover under an infliction of emotional distress claim she need not have suffered a direct physical injury.

In *Angus v. Shiley, Inc., supra*, our Court of Appeals held that although Pennsylvania law permits a cause of action in limited circumstances for intentional infliction of emotional distress even if the plaintiff suffers no direct physical injury, the Pennsylvania Supreme Court would not extend that recognition to a case where the "alleged wrongdoing was directed at a class of consumers rather than [at] a particular plaintiff."

Angus v. Shiley, Inc., 989 F.2d at 148; see *Brinkman v. Shiley, Inc.*, 732 F.Supp. 33 (M.D.Pa.1989). Judge Greenberg also pointed out for the Court in *Angus*:

> . . . If the Supreme Court of Pennsylvania recognized a cause of action for intentional infliction of emotional distress on the allegations of Angus's complaint, it effectively would sanction a large, if not vast, number of lawsuits by consumers who obtained properly functioning valves. We do not believe that it would do any such thing.

989 F.2d at 148 (footnote omitted).

Because the Pennsylvania Supreme Court has not spoken on this issue, we must follow the Court of Appeals' prediction in *Angus* and grant summary judgment in favor of defendants on this claim as well.

(c) Negligence

Plaintiff also claims that defendants negligently manufactured her heart valve. To prove negligence under Pennsylvania law, plaintiff must prove the following elements:

> 1) A duty or obligation recognized by the law, requiring the actor to conform to a certain standard of conduct for the protection of others against unreasonable risks;
>
> 2) A failure to conform to the standard required;
>
> 3) A causal connection between the conduct and the resulting injury; and
>
> 4) Actual loss or damage resulting to the interests of another.

Griggs v. BIC Corp., 981 F.2d 1429, 1434 (3d Cir.1992) (citing *Morena v. South Hills Health Sys.*, 501 Pa. 634, 462 A.2d 680, 684 n. 5 (1983)).

Plaintiff claims that defendants had a duty to exercise due care in the manufacturing of her heart valve, that they breached that duty, causing her to fear that her heart valve

would fail which resulted in her decision to have her Shiley heart valve explanted and replaced. We find, however, that Ms. Michael has submitted no evidence to show that defendants were negligent in the manufacture of her heart valve and, therefore, there is no evidence they breached any state law duty to her. Plaintiff proffers much evidence showing that defendants may have negligently manufactured *other* heart valves, but such evidence is not material to Ms. Michael's claim of negligence.

Ms Michael's argument also proves too much, as a homely analogy will show. Suppose Ms. Michael and a neighbor each own the same type of lawn mower. Ms. Michael learns that because of an accident with the lawn mower, her neighbor lost her foot. A jury held for the neighbor in the Court of Common Pleas. We are aware of no Pennsylvania Supreme Court case that would permit Ms. Michael to recover against the manufacturer for a replacement lawn mower when her lawn mower had been working properly, and there was no evidence that it had been manufactured negligently.[18]

Absent evidence that Ms. Michael's heart valve was manufactured negligently, we will grant summary judgment in favor of defendants on plaintiff's negligence claim.

(d) Negligent Failure to Warn

Plaintiff also claims that defendants were negligent because they failed to warn her about the possibility of strut fractures and about other potential defects. In order to satisfy the causation requirement in a negligent failure to warn cause of action, plaintiff must show that if defendants had issued a proper warning, plaintiff would have altered her behavior. *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492-493 (3d Cir.1985).

Ms. Michael's cardiologist stated that he thought the Shiley heart valve was the best available at the time of Ms.

---

[18] Our Court of Appeals, too, observed in *Angus* "that courts might not be able to draw a principled distinction between heart valves and other properly functioning products for liability purposes." 989 F.2d at 148 n.8.

Michael's first implant. Burke Dep., p. 58. He also stated that her valve "should be replaced and it should be replaced sooner as opposed to later." Burke Dep., p. 54. Plaintiff does not submit any evidence that she would have altered her behavior even if she had been warned in 1982. She makes no assertions that if she had known of the alleged dangers that she would not have had the valve implanted—it will be recalled that she would likely have died without the valve—or that she would not have had the valve replaced when there was another safer heart valve on the market. The evidence at most shows that Ms. Michael feared that her heart wasn't working properly and that her cardiologist thought she should have her mitral valve replaced. Michael Dep., p. 44-48.

Because Ms. Michael has not proffered evidence showing causation, defendants would be entitled to summary judgment even absent MDA-required preemption.

(e) Fraud Causing Disparagement

Ms. Michael also urges us to adopt her "fraud causing disparagement" theory of liability. Plaintiff has not cited any Pennsylvania decision supporting this cause of action, and it appears that no such authority exists. It is not for this Court to create a new state law cause of action. When our jurisdiction is solely based upon diversity, we may only apply the law as the Supreme Court of Pennsylvania has determined it. *See Wolk v. Saks Fifth Ave., Inc.*, 728 F.2d 221, 225 (1984).

Summary judgment is thus also appropriate for this cause of action.

(f) Alter Ego, Conspiracy, Respondeat Superior

Plaintiff alleges that defendant Pfizer is the parent of, and owns and controls, defendants Hospital Product Group, Inc. and Shiley, Inc. Plaintiff's Complaint, ¶¶ 50, 52. Plaintiff also claims that defendant Hospital Product Group, Inc. is a parent of and controls its wholly-owned subsidiary, defendant Shiley, Inc. Plaintiff's complaint, ¶ 51. Ms. Michael claims

that defendants' corporate structure is "a sham, legally ineffective and each defendant was the alter ego of the other and the acts and omissions of Shiley were the acts and omissions of its co-defendants." Plaintiff's Complaint, ¶ 53.

(1) Alter Ego

Courts may disregard corporate formalities, "pierce the corporate veil" and hold a parent corporation liable for a subsidiary's actions "whenever one in control of a corporation uses that control, or uses the corporate assets, to further his or her own personal interests." *Village at Camelback Property Owners Assn. v. Carr*, 371 Pa.Super. 452, 460, 538 A.2d 528, 533, (1988); *see Kiehl v. Action Mfg. Co.*, 517 Pa. 183, 190, 535 A.2d 571, 574 (1987). As we have discussed, defendant Shiley is not liable to Ms. Michael for any of its actions. There is no underlying liability for the actions of the subsidiary and, thus, even if we were to "pierce the corporate veil," there would be no liability for the parent. Therefore, we will grant summary judgment in favor of defendants on this claim, to the extent that it may be regarded as a subtantive, and not derivative, claim.

(2) Civil Conspiracy

Alternatively, Ms. Michael claims defendants conspired to make misrepresentations about heart valves and "to produce, market, sell and distribute the [Shiley heart valve] in [a] defective condition." Plaintiff's Complaint, ¶ 54. In order to establish civil conspiracy, Ms. Michael must show that there was "a combination or agreement between two or more persons to do an unlawful thing, or to do a lawful thing in an unlawful manner." *Fife v. Great Atlantic and Pacific Tea Co.*, 356 Pa. 265, 266, 52 A.2d 24, 27 (1947).

It is, of course, counterintuitive to accept the proposition that a parent corporation can conspire with its subsidiary. Thus, the Supreme Court has held in its antitrust jurisprudence that a parent and subsidiary are incapable of conspiring. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752,

104 S.Ct. 2731 (1984). *Copperweld*'s reasoning makes good sense here as well, since a subsidiary can no more "conspire" with its parent corporation than a human hand can "conspire" with its possessor's head.

Additionally, under Pennsylvania law it is essential to a cause of action for civil conspiracy that there be evidence of malice, *i.e.*, an intent to injure. *Thompson Coal Co. v. Pike Coal Co.*, 488 Pa. 198, 211, 412 A.2d 466, 472 (1979). Plaintiff has not alleged any malice directed toward her (as opposed to a class) in her complaint, nor has she submitted any evidence showing that defendants acted solely to injure her.

We therefore must grant summary judgment in favor of defendants.

(3) Respondeat Superior

Lastly, Ms. Michael claims defendants Pfizer and Hospital Product Group are liable under the doctrine of *respondeat superior.* The *respondeat superior* doctrine "holds . . . an employer . . . responsible for damages in a legal action for the acts or omissions of its servant [or] its employee." *Gajkowski v. International Brotherhood of Teamsters, etc.*, 519 Pa. 320, 332, 548 A.2d 533, 538 (1988). We can only infer that plaintiff alleges that defendant Shiley, Inc. is the servant or employee of defendants Pfizer and Hospital Product Group. Because we have found no liability against Shiley, there is no basis for *respondeat superior* liability. Therefore, we will grant summary judgment in favor of defendants on this claim as well.

* * *

We have held that the MDA has wholly preempted plaintiff's state law claims against defendants. Alternatively, we have held that the claims we have canvassed are merely rhetorical, given the fundamental, threshold barrier that plaintiff suffered no damage cognizable under Pennsylvania law. According to plaintiff's doctor, Shiley's valve kept her alive

for ten years, and showed no sign of imperfection. Plaintiff's anxiety, however sincere, cannot outweigh this hard and uncontroverted evidence.

We will therefore grant defendants' motions for summary judgment. An appropriate Order follows.

ORDER

AND NOW, this 25th day of February, 1994, upon consideration of defendants' motion for summary judgment, motion for partial summary judgment and the parties' submissions related to those motions, it is hereby ORDERED that:

1. Defendants' motion for summary judgment is GRANTED;

2. Defendants' motion for partial summary judgment is GRANTED IN PART on all claims except plaintiff's fraud claim; and

3. JUDGMENT IS ENTERED in favor of defendants and against plaintiff; and

4. The Clerk of the Court shall CLOSE this case statistically.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 94-1496
March 7, 1995, Decided

NINA MICHAEL,

Appellant,

—v.—

SHILEY, INC.; Hospital Products Group, Inc.,
(Formerly Howmedica, Inc.); Pfizer, Inc.

BEFORE: SLOVITER, Chief Judge, BECKER, STAPLETON, MANSMANN, GREENBERG, HUTCHINSON, SCIRICA, COWEN, NYGAARD, ALITO, ROTH, LEWIS, McKEE, SAROKIN and GARTH, Circuit Judges.

OPINION BY: Walter K. Stapleton

OPINION: SUR PETITION FOR REHEARING

The petition for rehearing filed by appellees in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied. Judge Roth would have granted the petition for rehearing.

By the Court,

Walter K. Stapleton
Circuit Judge

FOOTNOTE 8 FROM PETITION PAGE 10

See, Zuniga v. Blue Cross and Blue Shield, Nos. 93-1536, 93-1872, 1995 WL 251112 (6th Cir. 1995); *Taylor AG Indus. v. Pure-Gro Corp.*, No. 93-16852, 1995 WL 234993 (9th Cir. 1995); *Carstensen v. Brunswick Corp.*, 49 F.3d 430 (8th Cir. 1995); *Hodges v. Delta Airlines*, 44 F.3d 334 (5th Cir. 1995); *Lowe v. Sporicidin Intern.*, 47 F.3d 124 (4th Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir. 1995), *cert. denied*, 1995 WL 258615 (U.S. May 30, 1995) (No. 94-1754); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3rd Cir. 1995); *Resolution Trust Corp. v. Diamond*, 45 F.3d 665 (2d Cir. 1995), *petition for cert. filed*, 63 U.S.L.W. 3707 (U.S. Mar. 15, 1995) (No. 94-1528); *Bunning v. Kentucky.*, 42 F.3d 1008 (6th Cir. 1994); *National Broiler Council v. Voss*, 44 F.3d 740 (9th Cir. 1994); *Pic-A-State PA, Inc. v. Pennsylvania*, 42 F.3d 175 (3d Cir. 1994); *Karl Rove & Co. v. Thornburgh*, 39 F.3d 1273 (5th Cir. 1994); *Calhoun v. Yamaha Motor Corp.*, 40 F.3d 622 (3d Cir. 1994), *cert. granted*, 63 U.S.L.W. 3827 (U.S. May 22, 1995) (No. 94-1387); *Keams v. Tempe Technical Institute, Inc.*, 39 F.3d 222 (9th Cir. 1994); *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *Vango Media, Inc. v. City of New York*, 34 F.3d 68 (2d Cir. 1994); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Mobil Oil Corp. v. Virginia Gasline Marketers and Automotive Repair Ass'n Inc.*, 34 F.3d 220 (4th Cir. 1994), *cert. denied*, 115 S. Ct. 1097 (1995); *Simmons v. Mobil Oil Corp.*, 29 F.3d 505 (9th Cir. 1994); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Broyde v. Gotham Tower, Inc.*, 13 F.3d 994 (6th Cir. 1994), *cert. denied*, 114 S. Ct. 2137 (1994); *Southern Pacific Transp. Co. v. Public Utility Com'n*, 9 F.3d 807 (9th Cir. 1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *Kinley Corp. v. Iowa Utilities Bd.*, 999 F.2d 354 (8th Cir. 1993); *R.J. Corman R. R. Co. v. Palmore*, 999 F.2d 149 (6th Cir. 1993); *King v. E.I. Du Pont De Nemours & Co.*, 996 F.2d

1346 (1st Cir.), *cert. denied*, 114 S. Ct. 490 (1993); *Weber v. Heaney*, 995 F.2d 872 (8th Cir. 1993); *Public Health Trust v. Lake Aircraft, Inc.*, 992 F.2d 291 (11th Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993); *Toy Mfrs. of America, Inc. v. Blumenthal*, 986 F.2d 615 (2d Cir. 1992); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Home Mortg. Bank v. Ryan*, 986 F.2d 372 (10th Cir. 1993); *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438 (10th Cir.), *cert. denied*, 114 S. Ct. 291 (1993); *Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.), *cert. denied*, 114 S. Ct. 60 (1993); *Cooper v. American Auto. Ins. Co.*, 978 F.2d 602 (10th Cir. 1992); *Greenwood Trust Co. v. Massachusetts*, 971 F.2d 818 (1st Cir. 1992), *cert. denied*, 113 S. Ct. 974 (1993); *Petix v. Kabi Pharmacia Opthalmics, Inc.*, No. 92-CV-503A, 1995 WL 244606 (S.D.N.Y. 1995); *Richman v. W.L. Gore & Assoc. Inc.*, No. 94 Civ. 6397, 1995 WL 144067 (S.D.N.Y. 1995); *McMurtrie v. Iolab Corp.*, No. Civ. A. 94-3683, 1995 WL 120091 (E.D. La. 1995); *Borskey v. Medtronics, Inc.*, No. Civ. A. 94-2302, 1995 WL 120098 (E.D. La. 1995); *LeMay v. Eli Lilly & Co.*, No. Civ. A. 93-C-0142, 1995 WL 139972 (D. Wis. 1995); *Burton v. R.J. Reynolds Tobacco Co.*, No. 94-2202, 1995 WL 148356 (D. Kan. 1995); *City of South Bend v. Consolidated Rail Corp.*, No. 3:95-CV-29RM, 1995 WL 129069 (D. Ind. 1995); *Rowley v. American Airlines*, 875 F.Supp. 708 (D. Or. 1995); *Bokis v. American Medical Sys. Inc.*, 875 F.Supp. 748 (W.D. Okla. 1995); *Haas v. Group Health Plan, Inc.*, 875 F.Supp. 544 (S.D. Ill. 1994); *NVMercure Ltd. Partnership v. Resolution Trust Corp.*, 871 F.Supp. 488 (D.D.C. 1994); *Helms v. Sporicidin Intern.*, 871 F.Supp. 873 (E.D.N.C. 1994); *Miller v. E. I. Du Pont De Nemours & Co.*, No. Civ. A. 493CV26, 1994 WL 774574 (D. Miss. 1994); *Cooperative Communi-*

cations, Inc. v. AT & T Corp., 867 F.Supp. 1511 (D. Utah 1994); *Association of Intern. Auto Mfrs., Inc. v. Abrams*, 867 F.Supp. 248 (S.D.N.Y. 1994); *Rombom v. United Air Lines*, 867 F.Supp. 214 (S.D.N.Y. 1994); *Mitchell v. Collagen Corp.*, 870 F.Supp. 885 (N.D. Ind. 1994); *Sowers v. Johnson & Johnson Medical, Inc.*, 867 F.Supp. 306 (E.D. Pa 1994); *Oliver v. Johnson & Johnson, Inc.*, 863 F.Supp. 251 (W.D. Pa 1994); *Higgins v. Monsanto Co.*, 862 F.Supp. 751 (N.D.N.Y. 1994); *Roberson v. E.I. Dupont De Nemours & Co.*, 863 F.Supp. 929 (W.D. Ark. 1994); *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D. La. 1994); *Grenier v. Vermont Log Buildings, Inc.*, No. Civ. A. 91-40115-NM6, 1994 WL 523869 (D. Mass. 1994); *Burnett v. Pfizer, Inc.*, 864 F.Supp. 25 (E.D. Ky. 1994); *Committee of Dental Amalgam Alloy Mfrs. v. Henry*, 871 F.Supp. 1278 (S.D. Cal. 1994); *Talbott v. C.R. Bard, Inc.*, 865 F.Supp. 37 (D. Mass. 1994); *Ginochio v. Surgikos, Inc.*, 864 F.Supp. 948 (N.D. Cal. 1994); *Penn Advertising of Baltimore, Inc. V. Mayor of City of Baltimore*, 862 F.Supp. 1402 (D. Md. 1994); *In re Dupont-Benlate Litigation*, 859 F.Supp. 619 (D.P.R. 1994); *Ministry of Health v. Shiley Inc.*, 858 F.Supp. 1426 (C.D. Cal. 1994); *Kenepp v. American Edwards Labs*, 859 F.Supp. 809 (E.D. Pa. 1994); *Pitts v. Dow Chemical Co.*, 859 F.Supp. 543 (M.D. Ala. 1994); *Jillson v. Vermont Log Bldgs., Inc.*, 857 F.Supp. 985 (D. Mass. 1994); *Eppler v. Ciba-Geigy Corp.*, 860 F.Supp. 1391 (W.D. Mo. 1994); *Parenteau v. Johnson & Johnson Orthopedics, Inc.*, 856 F.Supp. 61 (D.N.H. 1994); *Tammen v. General Motors Corp.*, 857 F.Supp. 788 (D. Kan. 1994); *English v. Mentor Corp.*, No. Civ. A. 93-2725, 1994 WL 263353 (E.D. Pa. 1994); *Montag v. Honda Motor Co.*, 856 F.Supp. 574 (D. Colo. 1994); *Hayden v. Blue Cross and Blue Shield*, 855 F.Supp. 344 (M.D. Ala. 1994); *Prather v. Ciba-Geigy Corp.*, 852 F.Supp. 530 (W.D. La. 1994); *Corrigan v. Methodist Hosp.*, 853 F.Supp. 832 (E.D. Pa. 1994); *Brown v. Medtronic, Inc.*, 852 F.Supp. 717 (S.D. Ind. 1994); *Mulligan v. Pfizer Inc.*, 850 F.Supp. 633 (S.D. Ohio 1994); *Kemp v. Pfizer, Inc.*, 851 F.Supp. 269 (E.D. Mich. 1994); *Duvall v. Bristol-Myers Squibb Co.*, No. Civ. S-

93-1072, 1994 WL 591534 (D. Md. 1994); *Contant v. Kawasaki Motors Corp.*, 848 F.Supp. 170 (M.D. Fla. 1994); *Bingham v. Terminix Intern. Co.*, 850 F.Supp. 516 (S.D. Miss. 1994); *Byrnes v. Honda Motor Co.*, 845 F.Supp. 875 (S.D. Fla. 1994); *Allen v. Pennco Engineering Co.*, 847 F.Supp. 1315 (M.D. La. 1994); *Trinity Mountain Seed Co. v. MSD Agvet*, 844 F.Supp. 597 (D. Idaho 1994); *DeHaan v. Whink Products Co.*, No. 91-C-0014, 1994 WL 24322 (N.D. Ill. 1994); *Bravman v. Baxter Healthcare Corp.*, 842 F.Supp. 747 (S.D.N.Y. 1994); *Griffin v. Medtronic, Inc.*, 840 F.Supp. 396 (D. Md. 1994); *Allstate Ins. Co. v. Pooltime Products, Inc.*, 846 F.Supp. 499 (E.D. La. 1994); *Quad R. Farms v. American Cyanamid Co.*, 840 F.Supp. 694 (D. Minn. 1993); *Elbert v. Howmedica, Inc.*, 841 F.Supp. 327 (D. Haw. 1993); *Ferrara v. Intermedics Intraocular, Inc.*, No. Civ. A. 93-0404, 1993 WL 533973 (E.D. La. 1993); *Lewis v. Intermedics Intracocular, Inc.*, No. Civ. A. 93-0007, 1993 WL 533981 (E.D. La. 1993); *Angelle v. Intermedics Intraocular, Inc.*, No. Civ. A. 93-0403, 1993 WL 533983, (E.D. La. 1993); *Hamilton v. Surgidev Corp.*, No. Civ. A. 92-3466, 1993 WL 533994 (E.D. La. 1993); *O'Hern v. Delta Airlines*, 838 F.Supp. 1264 (N.D. Ill. 1993); *Kinser v. Ciba-Geigy Corp.*, 837 F.Supp. 217 (W.D. Ky. 1993); *Der Gazarian v. Dow Chemical Co.*, 836 F.Supp. 1429 (W.D. Ark. 1993); *Kemp v. Pfizer, Inc.*, 835 F.Supp. 1015 (E.D. Mich. 1993); *Doricent v. American Airlines*, No. Civ. A. 91-12084Y, 1993 WL 437670 (D. Mass. 1993); *Wright v. Dow Chemical U.S.A.*, 845 F.Supp. 503 (M.D. Tenn. 1993); *Shots v. CSX Transp., Inc.*, No. TH 91-125-C, 1993 WL 764340 (S.D. Ind. 1993); *Gills v. Ford Motor Co.*, 829 F.Supp. 894 (W.D. Ky. 1993); *Reiter v. Zimmer, Inc.*, 830 F.Supp. 199 (S.D.N.Y. 1993); *Flynn v. Biomet, Inc.*, No. Civ. A. 3:93CV192, 1993 WL 540570 (E.D. Va. 1993); *Jack v. Trans World Airlines*, 820 F.Supp. 1218 (N.D. Cal. 1993); *Herndon v. Brown & Williamson Tobacco Corp.*, No. 1:92:CV:166, 1993 WL 475530 (W.D. Mich. 1993); *Sprint Corp. v. Evans*, 818 F.Supp. 1447 (M.D. Ala. 1993); *Davis v. Brunswick Corp.*, 854 F.Supp. 1574 (N.D. Ga. 1993);

Levesque v. Miles Inc., 816 F.Supp. 61 (D.N.H. 1993); *MacDonald v. Monsanto Co.*, 813 F.Supp. 1258 (E.D. Tex. 1993); *Margolis v. United Airlines*, 811 F.Supp. 318 (E.D. Mich. 1993); *Burlington Northern R. Co. v. City of Connell*, 811 F.Supp. 1459 (E.D. Wash. 1993); *Gray v. Quaker Fabric Corp.*, 809 F.Supp. 163 (D. Mass. 1992), *aff'd*, 6 F.3d 849 (1st Cir. 1993); *Country Aviation, Inc. v. Tinicum Tp.*, No. Civ. A. 91-12624-Y, 1992 WL 396782 (E.D. Pa. 1992); *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (3d Cir. 1993); *Casper v. E.I. Du Pont De Nemours & Co.*, 806 F.Supp. 903 (E.D. Wash. 1992); *Gibson v. Dow Chemical Co.*, 842 F.Supp. 938 (E.D. Ky. 1992); *Couture v. Dow Chemical U.S.A.*, 804 F.Supp. 1298 (D. Mont. 1992); *Burke v. Dow Chemical Co.*, 797 F.Supp. 112 (E.D.N.Y. 1992); *Ambrosio v. Barnes-Hind, Inc.*, No. 72243, 1995 WL 259920 (N.Y. App. Div. 1995); *Connelly v. Iolab Corp.*, No. WD49377, 1995 WL 250794 (Mo. Ct. App. 1995); *Reese v. Payless Drug Stores Northwest, Inc.*, 40 Cal. Rptr. 2d 75 (Ct. App. 1995); *Malone v. American Cyanamid Co.*, No. 4-94-0811, 1995 WL 217513 (Ill. Ct. App. 1995); *Hopkins v. American Cyanamid Co.*, No. 26,721 CA, 1995 WL 146224 (La. Ct. App. 1995); *Ryan v. Mercury Marine*, No. 163473, 1995 WL 153575 (Mich. Ct. App. 1995); *Louisiana-Pacific Corp. v. Koppers Co.*, 38 Cal. Rptr.2d 257 (Ct. App. 1995); *Berger v. Medtronic, Inc.*, 623 N.Y.S.2d 985 (Sup. Ct. 1995); *Busch v. Graphic Color Corp.*, 644 N.E.2d 839 (Ill. Ct. App. 1995); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214, (Ill. Ct. App. 1995); *Wilson v. Pleasant*, 645 N.E.2d 638 (Ind. Ct. App. 1994); *Jenkins v. Amchem Products, Inc.*, 886 P.2d 869 (Kan. 1994); *Anderson v. Evergreen Intern. Airlines*, 886 P.2d 1068 (Or. Ct. App. 1994), *rev. denied*, 891 P.2d 659 (Or. 1995); *Messina v. Smith & Nephew Richards, Inc.*, No. 92C-01-018, 1994 WL 750318 (Del. Super. 1994); *Harris v. Chase Manhattan Bank, N.A.*, 35 Cal. Rptr.2d 733 (Ct. App. 1994), *rev. granted*, 889 P.2d 540 (Cal. 1995); *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206 (Ill. Ct. App. 1994), *appl. allowed*, 647 N.E.2d 1009 (Ill. 1995); *Merrell Dow Pharmaceuticals, Inc.*

v. Oxendine, 649 A.2d 825 (D.C. App. 1994); *Dykema v. Volkswagenwerk AG*, 525 N.W.2d 754 (Wis. Ct. App. 1994), *rev. denied*, No. 93-1341, (Wis. Feb. 21, 1995); *June v. Laris*, 618 N.Y.S.2d 138 (App. Div. 1994); *Hernandez-Gomez v. Leonardo*, 884 P.2d 183 (Ariz. 1994), *vacated in light of, Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995); *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr.2d 852 (Ct. App. 1994); *Fogal v. Steinfeld*, 620 N.Y.S.2d 875 (Sup. Ct. 1994); *Elam v. Quest Chemical Corp.*, 884 S.W.2d 907 (Tex. Ct. App. 1994); *Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Tex. Ct. App. 1994); *Figgs v. Bellevue Holding Co.*, 652 A.2d 1084 (Del. Super. 1994); *Warner v. American Fluoride Corp.*, 616 N.Y.S.2d 534 (App. Div. 1994); *Miranda v. Fridman*, 647 A.2d 167 (N.J. Super.), *certification denied*, 649 A.2d 1291 (N.J. 1994); *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998 (Ohio 1994); *Harrell v. Champlain Enterprises Inc.*, 613 N.Y.S.2d 1002 (App. Div. 1994); *Mangini v. R.J. Reynolds Tobacco Co.*, 875 P.2d 73 (Cal.), *cert. denied*, 115 S. Ct. 577 (1994); *ISK Biotech Corp. V. Douberly*, 640 So.2d 85 (Fla. Ct. App. 1994); *Loulos v. Dick Smith Ford, Inc.*, 882 S.W.2d 149 (Mo. Ct. App. 1994); *Green v. Dolsky*, 641 A.2d 600 (Pa. Super.), *appl. granted*, 652 A.2d 1324 (Pa. 1994); *Moore v. Brunswick Bowling & Billiards Corp.*, 889 S.W.2d 246 (Tex.), *cert. denied sub nom., Vivian Indus. Plastics, Inc. v. Moore*, 115 S. Ct. 664 (1994); *Salazar v. Whink Products Co.*, 881 P.2d 431 (Colo. Ct. App. 1994), *cert. denied*, 115 S. Ct. 1315 (1995); *Brotherhood of Maintenance of Way Employees v. Chicago and North Western Transp. Co.*, 514 N.W.2d 90 (Iowa), *cert. denied sub nom., Otis v. Chicago & North Western Transp. Co.*, 115 S. Ct. 198 (1994); *Williams v. State*, 640 So.2d 365 (La. Ct. App. 1994); *State ex rel. Jones Chemicals, Inc. v. Seier*, 871 S.W.2d 611 (Mo. Ct. App. 1994); *Banner Advertising, Inc. v. City of Boulder*, 868 P.2d 1077 (Colo. 1994); *ICI Americas, Inc. v. Banks*, 440 S.E.2d 38 (Ga. Ct. App. 1993), *aff'd in part, rev'd in part*, 450 S.E.2d 671 (Ga. 1994); *Muzzy v. E.I. Du Pont De Nemours & Co.*, No. CX-92-275, 1993 WL 761991 (Minn. Dist. Ct. 1993); *Moody v.*

Chevron Chemical Co., 505 N.W.2d 900 (Mich. Ct. App. 1993), *appl. denied*, 525 N.W.2d 450 (Mich. 1994); *Macrie v. SDS Biotech Corp.*, 630 A.2d 805 (N.J. Super.), *appl. dism'd*, 636 A.2d 522 (N.J. 1993); *Emery v. Southern Ry. Co.*, 866 S.W.2d 557 (Tenn. Ct. App. 1993); *Boyle v. Chrysler Corp.*, 501 N.W.2d 865 (Wis. Ct. App.), *rev. denied*, 510 N.W.2d 137 (Wis. 1993); *Brennan v. Dow Chemical Co.*, 613 So.2d 131 (Fla. Ct. App. 1993); *Marrs v. Ford Motor Co.*, 852 S.W.2d 570 (Tex. Ct. App. 1993); *Farner v. Brunswick Corp.*, 607 N.E.2d 562, (Ill. Ct. App.), *appl. denied*, 616 N.E.2d 333 (Ill. 1993); *Vail v. Pan Am Corp.*, 616 A.2d 523 (N.J. Super. 1992); *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992); *Davidson v. Velsicol Chemical Corp.*, 834 P.2d 931 (Nev. 1992), *cert. denied*, 113 S. Ct. 1994 (1993); *Johnson v. North Carolina Dept. of Transp.*, 418 S.E.2d 700 (N.C. Ct. App. 1992); *Yowell v. Chevron Chemical Co.*, 863 S.W.2d 62 (Mo. Ct. App. 1992).

No. 94-1971 (2)

Supreme Court, U.S.
FILED
AUG 30 1995
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

SHILEY INC.; Hospital Products Group, Inc.,
(Formerly Howmedica, Inc.); Pfizer, Inc.,

Petitioners,

—against—

NINA MICHAEL,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONERS

DAVID KLINGSBERG
KAYE, SCHOLER, FIERMAN,
HAYS & HANDLER
425 Park Avenue
New York, New York 10022
(212) 836-8000

Counsel of Record for Petitioners

14 pp

TABLE OF CONTENTS

PAGE

INTRODUCTION 1

ARGUMENT

Numerous Pending Cases Involve Litigation Of The Same Issues Of Federal Preemption That Are Presented Here 2

A. Other Medical Device Litigation 3

B. Cases and Claims Involving The Shiley C/C Heart Valve 4

CONCLUSION 9

TABLE OF AUTHORITIES

Cases

PAGE

Baker v. Firestone Tire & Rubber Co., 793 F.2d 1196 (11th Cir. 1986) 8

Beavers v. Shiley, Inc., G-95-432 (S.D. Tex.) 4

Borskey v. Medtronic, Inc., 1995 WL 120098 (E.D. La. March 15, 1995) 3

Burke v. Pfizer, Inc., MON-L-0101-93 (N.J. Super Ct., Monmouth County) 5

Burnett v. Pfizer, Inc., 864 F. Supp. 25 (E.D. Ky. 1994) 6

Cameron v. Howmedica, 820 F. Supp. 317 (E.D. Mich. 1993) 7

English v. Mentor Corp., 1994 WL 263353 (E.D. Pa. June 13, 1994) 3

Flynn v. Biomet, Inc., 1993 WL 540570 (E.D. Va. July 23, 1993)..... 3

Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994) 3

Hamilton v. Surgidev Corp., 1993 WL 533994 (E.D. La. Dec. 10, 1993) 7

Hartz v. Shiley, Inc., et al., BC130340 (Cal. Super. Ct., Los Angeles County) 4

Kemp v. Pfizer, Inc., Sixth Circuit Case No. 94-1502, on appeal from 835 F. Supp. 1015 (E.D. Mich. 1993), and 851 F. Supp. 269 (E.D. Mich. 1994) 4, 5, 6, 7

Khan v. Shiley, Inc. (Cal. Super. Ct., Orange County). 4

PAGE

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 1

Knight Pub. Co. v. U.S. Dept. of Justice, 631 F. Supp. 1175 (W.D.N.C. 1986) 8

Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426 (C.D. Cal. 1994) 6

Mitchell v. Collagen Corp., 870 F. Supp. 885 (N.D. Ind. 1994) 4

Murray v. Medtronic, Inc., 1993 WL 515741 (E.D. La. Dec. 3, 1993) 3

Pearce v. E.F. Hutton Group, Inc., 653 F. Supp. 810 (D.D.C. 1987) 8

Richman v. W.L. Gore & Associates, Inc., 881 F. Supp. 895 (S.D.N.Y. 1995) 3

Rivera v. Shiley, Inc. (Pa. Ct. of Common Pleas, Philadelphia County) 5

Saitta v. Shiley, Inc., Civil Action No. 2:95cv02330 (D.N.J.) 4, 6

Talbott v. C.R. Bard, Inc., __ F.3d __, 1995 WL 470265 (1st Cir. August 14, 1995) 1, 3

Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993).. 8

Statutes

1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C.A. § 360c et seq. (Supp. 1995)) 1

Articles

PAGE

Collins, "The Evolution of Artificial Heart Valves," 324 *New Eng. J. Med.*, 624, 626 (Feb. 28, 1991). 4

Petitioners submit this reply brief in support of their Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

INTRODUCTION

The decision below, in conflict with other Circuit Courts of Appeals as set forth in the Petition, held that respondent's claims of fraud on the medical community and breach of express warranty concerning a medical device (the Shiley "c/c valve") were not preempted by the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.[1]

After the Petition was filed, the First Circuit, in *Talbott v. C.R. Bard*, __ F.3d __, 1995 WL 470265 (1st Cir. August 14, 1995), again held that an express warranty claim is preempted by the MDA, thus reiterating its previous decision in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993). The First Circuit expressly stated in *Talbott* that "the Third Circuit's position [in *Michael*] appears to be inconsistent with this circuit's position as set forth in *King* . . . ." *Talbott*, 1995 WL 470265, at *6. That is contrary to respondent's argument that the decision below was not inconsistent with *King* on this issue (Respondent's Brief in Opposition ["Opp. Br."] at 16).

Respondent's principal argument is that this case is unique, either because of the underlying facts or the nature of her claims, and therefore is not appropriate for certiorari. In fact, the case raises legal issues which have come up repeatedly in the past, are pending in numerous different cases today, and will continue to arise in the future in cases involving both the c/c valve and other medical devices.

The fact that Shiley ceased marketing the c/c valve after respondent's implant, and that the valve's FDA approval was then withdrawn, does not make this case unique or otherwise

---

[1] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C.A. § 360c *et seq.* (Supp. 1995)).

exempt respondent's claims from preemption. Implantable devices to replace human organs or organ parts are a rapidly developing field, and devices are regularly replaced by newer models. If claims involving a withdrawn device were held outside the scope of the MDA's preemption provision, the result would be a multitude of new lawsuits—lawsuits that would threaten continued research and development of these vitally needed products, and negate the MDA's express purpose to promote and encourage new devices.

Accordingly, this Court's grant of certiorari would provide needed guidance to the lower courts. Review would also promote judicial efficiency, by avoiding repeated litigation of the preemption issue in numerous other medical device cases, and by avoiding protracted discovery and trials in federal and state courts, if this Court holds that claims like respondent's are preempted.

ARGUMENT

Numerous Pending Cases Involve Litigation Of The Same Issues Of Federal Preemption That Are Presented Here.

Respondent's "uniqueness" argument fails at two levels. First of all, many cases involving other class III medical devices raise the same issues of federal preemption under the MDA that are raised in the Petition. None of the facts that respondent cites concerning the c/c valve make the preemption issues in this case different. Secondly, there are many other pending cases (as well as prospective future cases) involving the c/c valve—the same make and model of medical device at issue here. All of those cases, therefore, involve the same alleged Shiley conduct that respondent cites as being unique to her case. In particular, it is routine in c/c valve cases for plaintiffs to allege a breach of the same express warranty, and rely on the same alleged misrepresentations to the medical community, that respondent relies on here.

A. Other Medical Device Litigation

Federal preemption of warranty and fraud claims similar to those here arises in a plethora of product liability litigations involving other medical devices.

The legal issue of whether the MDA preempts express warranty claims for medical devices has arisen in at least the following cases, with varying results: *Talbott v. C.R. Bard, Inc.*, __ F.3d __, 1995 WL 470265, at *6 (1st Cir. August 14, 1995) (preempted, cardiac catheter); *English v. Mentor Corp.*, 1994 WL 263353, *1, 8-9 (E.D. Pa. June 13, 1994) ("express warranties of merchantability" preempted, penile prosthesis); *Borskey v. Medtronic, Inc.*, 1995 WL 120098, at *2 (E.D. La. March 15, 1995) (preempted, drug pump); *Flynn v. Biomet, Inc.*, 1993 WL 540570, at *7 (E.D. Va. July 23, 1993) (preempted to the extent based upon "product packaging and labeling that was subject to FDA approval", hip joint prosthesis); *Murray v. Medtronic, Inc.*, 1993 WL 515741, at *2 (E.D. La. Dec. 3, 1993) (preempted as to Class III components, dorsal column stimulator); *Richman v. W.L. Gore & Associates, Inc.*, 881 F. Supp. 895, 904-05 (S.D.N.Y. 1995) (not preempted, ligament prosthesis).

The same issue will continue to recur in other medical device litigations. Respondent argues that the c/c valve's written warranty was unusual (Opp. Br. at 19-20). She does not explain, however, why or how the particular warranty terms in a particular case affect the *legal* issue of whether the Third Circuit in *Michael* correctly held, relying on *Cipollone*, that express warranty claims do not impose state requirements subject to MDA preemption. That issue is unaffected by the terms of the warranty. A grant of review leading to resolution of that issue would have broad application.

Claims similar to the fraud claim held not preempted below also occur in other medical device litigations. For example, in *Griffin v. Medtronic, Inc.*, 840 F. Supp. 396, 397 (D. Md. 1994), a pacemaker case, plaintiff specifically claimed "fraud

on the medical community."[2] *See also Mitchell v. Collagen Corp.*, 870 F. Supp. 885, 897 (N.D. Ind. 1994) ("claims with respect to fraud in advertising" preempted, injectable anti-wrinkle device). Further, if the decision below stands holding that such fraud claims are not preempted, more claims of that type will be made. Any user of a normally functioning product could allege, based on a small percentage of failures over the years, that the manufacturer fraudulently failed to disclose the risks associated with the product. Most implantable devices experience some complications, side effects, or failures in a small percentage of cases because their performance cannot be fully evaluated without years of experience with thousands of patients, and they cannot be inspected while implanted. Collins, "The Evolution of Artificial Heart Valves," 324 *New Eng. J. Med.*, 624, 626 (Feb. 28, 1991).

B. Cases and Claims Involving The Shiley C/C Heart Valve

There are currently at least 13 pending cases involving the c/c valve, other than this one. Eight cases are pending in state court in California, five of which involve plaintiffs who, like respondent, surgically replaced c/c valves that had never failed or malfunctioned. Other such c/c valve replacement cases are pending in the Southern District of Texas, and the District of New Jersey. Shiley c/c valve cases of other types are pending in the U.S. Court of Appeals for the Sixth Circuit, and in state courts in Pennsylvania and New Jersey.[3]

---

[2] In the course of holding plaintiff's other claims (including fraud) preempted, the court did not decide whether the fraud on the medical community claim was preempted, but rather found that claim barred under state law. 840 F. Supp. at 397.

[3] Seven of the eight California cases are consolidated under the case name *Khan v. Shiley, Inc.* (Cal. Super. Ct., Orange County). The other cases are *Hartz v. Shiley, Inc., et al.*, BC130340 (Cal. Super. Ct., Los Angeles County); *Beavers v. Shiley, Inc.*, G-95-432 (S.D. Tex.); *Saitta v. Shiley, Inc.*, Civil Action No. 2:95cv02330 (D.N.J.); *Kemp v. Pfizer, Inc.*, Sixth Circuit Case No. 94-1502, on appeal from 835 F. Supp.

Federal preemption is at issue in all these cases. *Kemp v. Pfizer, Inc.*, reported at 835 F. Supp. 1015 (E.D. Mich. 1993) and 851 F. Supp. 269 (E.D. Mich. 1994), is on appeal to the Sixth Circuit from a grant of summary judgment on the ground of federal preemption. In the California state court cases, the court denied two earlier preemption motions in other California c/c valve cases; but petitioners would promptly file preemption motions again in the pending cases, as appropriate under this Court's decision if review is granted here. Preemption in the District of New Jersey case is currently governed by the decision below. Petitioners also anticipate filing motions based on federal preemption in the Pennsylvania and New Jersey state court cases.

In addition to these pending cases, petitioners currently face approximately two dozen unfiled c/c valve claims, most involving circumstances where, like here, the claimant surgically replaced a functioning c/c valve. Each of these claims is a potential litigation; and the value of each as a claim, as well as its outcome as a litigation, depends in part on resolution of the same federal preemption issues that are presented by the Petition for Certiorari here.

The same is true of the c/c valve matters that can be expected in the future, as additional valves are replaced and/or experience an alleged failure or malfunction. Today, there are approximately 45,000 c/c artificial valves still implanted in living persons. When people replace a valve (or other device) for a more up to date model, they often also choose to sue the manufacturer of the earlier device. Thus, such lawsuits involving replaced c/c valves will likely continue to be filed for years to come.[4]

1015 (E.D. Mich. 1993), and 851 F. Supp. 269 (E.D. Mich. 1994); *Rivera v. Shiley, Inc.* (Pa. Ct. of Common Pleas, Philadelphia County); *Burke v. Pfizer, Inc.*, MON-L-0101-93 (N.J. Super. Ct., Monmouth County).

[4] Respondent's assertion at p. 20 of her brief, that "the vast majority of future fracture and reoperation claims are governed by" the *Bowling* settlement, is grossly misleading. *Bowling* settled claims relating to

The history of c/c valve litigation demonstrates that preemption is repeatedly raised and litigated, with inconsistent results. For example, while the Third Circuit in *Michael* held that a claim alleging breach of express warranty was not preempted, the court in *Kemp v. Pfizer, Inc.*, 851 F. Supp. 269, 273-74 (E.D. Mich. 1994)—which involved the same express warranty as *Michael*[5]—held just the opposite, ruling that this claim was preempted by § 360k(a). Contrary to the Third Circuit, which found this Court's decision on express warranty in *Cipollone* applicable to MDA preemption of that claim, the *Kemp* court reasoned that "given the differences in the [MDA and Smoking Act] statutes, the analysis undertaken in *Cipollone* is distinguishable." 851 F. Supp. at 273 n.1.

Similarly, in *Burnett v. Pfizer, Inc.*, 864 F. Supp. 25, 26 (E.D. Ky. 1994), the court held—also contrary to the Third Circuit's decision in *Michael*—that a fraud claim regarding Shiley's conduct in connection with the c/c valve was preempted by the MDA. *Contra Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426 (C.D. Cal. 1994) (holding that express warranty and fraud claims regarding the c/c valve were not preempted).

In sum, there is ample basis for a grant of certiorari to avoid repeated litigation and appeals of the preemption issue in the lower courts.

Shiley's request to withdraw the FDA's pre-market approval ("PMA") for the c/c valve, after Shiley ceased marketing the valve, does not undercut this case's applicability to the gen-

---

fear of future fracture of a working c/c valve. As to "fracture" (malfunction) and "reoperation" (replacement) claims, *Bowling* merely requires a formula-based automatic settlement offer, which the claimant is free to reject. Many claimants do reject these offers, including, for example, the plaintiff in *Saitta, supra*, who is represented by the same law firm that is co-counsel to respondent Michael in this case.

[5] As in *Michael*, the express warranty at issue in *Kemp* was a "warranty of reasonable care in the manufacture of the artificial heart valve at issue." 851 F. Supp. at 273.

eral run of medical device product liability litigations. (*See* Opp. Br. at 20-21). Every medical device is eventually withdrawn from the market and replaced by new models, particularly so in the rapidly developing field of replacements of human organs or parts thereof. The fact that the c/c valve is no longer being implanted is neither relevant, nor unusual.

Withdrawal of the PMA is equally irrelevant. The court below, in holding that most of respondent's claims were preempted, necessarily concluded that withdrawal of the PMA did not affect preemption; and respondent has filed no cross-petition seeking review on that issue.[6] Moreover, the court below was plainly correct in rejecting this argument. "If the preemption protection afforded by the MDA were removed once a faulty device was pulled from the market, then the fear and hesitancy in developing original and ground-breaking medical devices that Congress meant to alleviate would always remain as a bar to the development of needed devices that are potentially dangerous". *Kemp*, 835 F. Supp. at 1023.[7] If an implied exception were created to the express preemption doctrine for medical devices that are no longer sold or have a current PMA, that exception would swallow the rule. Artificial replacements for human organs or vital organ parts are continually being withdrawn from use and replaced by improved devices. Holding that the benefits of federal preemption are retroactively lost where a PMA has been voluntarily withdrawn, or terminated for any reason, would mean that virtually every federally-regulated medical device ultimately would be subject to retroactive state requirements—squarely contrary to Congress' express intent in enacting § 360k.

---

[6] The district court, in its decision, explicitly held that withdrawal of the PMA makes no difference. App. at 50a-51a n.11.

[7] *Accord Hamilton v. Surgidev Corp.*, 1993 WL 533994 (E.D. La. Dec. 10, 1993) (preemption despite withdrawal of intraocular lens and its IDE exemption); *Cameron v. Howmedica*, 820 F. Supp. 317 (E.D. Mich. 1993) (claim based on artificial hip which had 25% failure rate and had been removed from the market after two years held to be preempted).

The various other facts that respondent discusses in her opposition brief, principally at pp. 3-8, also have nothing to do with the legal issues raised by the Petition. They are simply respondent's alleged facts in support of her fraud and breach of warranty claims, all of which would be controverted and/or placed in proper context at trial if the claims are not held preempted.[8]

---

[8] The Third Circuit did not find any of these alleged facts, but merely assumed them to be true for purposes of ruling on the grant of summary judgment (App. at 7a). Moreover, of the two documents on which respondent principally relies, one is a report prepared in 1990 by the majority staff of a Congressional subcommittee—it is not a "Report of the Subcommittee" or a "House Report" as respondent disingenuously cites it (Opp. Br. at 4 n.2). The other document is a memorandum by three FDA employees that was never adopted by the agency. These documents are inadmissible. *See, e.g., Baker v. Firestone Tire & Rubber Co.*, 793 F.2d 1196, 1199 (11th Cir. 1986) (subcommittee report "consisted of the rather heated conclusions of a politically motivated hearing"). *Accord Pearce v. E.F. Hutton Group, Inc.*, 653 F. Supp. 810, 816 (D.D.C. 1987); *Knight Pub. Co. v. U.S. Dept. of Justice*, 631 F. Supp. 1175, 1178 (W.D.N.C. 1986). *Toole v. McClintock*, 999 F.2d 1430, 1433-34 (11th Cir. 1993) ("The tentative and second-hand nature of the findings in the FDA report should have kept it out of evidence"; reversing judgment for plaintiff). Further, while petitioners in 1994 settled claims under the False Claims Act, there was no "fine" and no finding or admission of liability. (Opp. Br. at 8-9 n.7).

CONCLUSION

For the reasons stated above, and all the reasons set forth in the Petition, Certiorari should be granted.

Dated: August 30, 1995

Respectfully submitted,

DAVID KLINGSBERG
KAYE, SCHOLER, FIERMAN,
HAYS & HANDLER
425 Park Avenue
New York, New York 10022
(212) 836-8000

Counsel of Record for Petitioners

(3)

Supreme Court, U.S.
FILED
AUG 0 2 1995
OFFICE OF THE CLERK

No. 94-1971

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

SHILEY, Inc.; Hospital Products Group, Inc. (formerly Howmedica, Inc.); Pfizer, Inc.

Petitioners,

v.

NINA MICHAEL,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

Gary Green
(Counsel of Record)
Sidkoff, Pincus & Green
1101 Market Street
2700 ARAMark Tower
Philadelphia, PA 19107
(215) 574-0600

Attorney for Respondent

42 pp

QUESTION PRESENTED

In a case involving the unique circumstances of a defective artificial heart valve prone to catastrophic failure, whose marketing approval was withdrawn by the Food and Drug Administration at petitioners' request, was the court of appeals correct in holding that respondent's state-law personal-injury claims for fraud on her and her physicians and for breach of express written warranty were not preempted by a provision that bars states from establishing certain device "requirements" that are "different from, or in addition to" requirements "applicable to [a] device" under the Medical Device Amendments to the Food, Drug and Cosmetic Act?

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF AUTHORITIES v

RESPONDENT'S BRIEF IN OPPOSITION 1

STATUTES AND REGULATIONS INVOLVED 3

STATEMENT OF THE CASE 3

A. The History of the C-C Valve 4

B. Respondent's Lawsuit And The Decisions Below 9

REASONS FOR DENYING THE WRIT 11

A. The Decision Below Is Not In Conflict With Decisions Of This Court and There Is No Significant Conflict Of Lower Court Authority. 12

1. Fraudulent Promotion of the C-C Valve. 13

2. Breach of Express Warranty. 16

B. The Unique Circumstances of Respondent's Case and the Regulatory History of the C-C Valve Make This Case A Poor Vehicle For Considering The General Scope Of MDA Preemption. 19

C. Because Congress Did Not Intend The MDA To Preempt Any State-Law Damages Claims, The Third Circuit's Rulings On The Fraud And Express Warranty Claims Are Plainly Correct. 21

CONCLUSION 27

TABLE OF AUTHORITIES

CASES **PAGE**

American Airlines, Inc. v. Wolens, 115 S. Ct. 817 (1995) 2, 10, 18

Bowling v. Pfizer, 143 F.R.D. 141 (S.D. Ohio 1992), *appeal dismissed*, 14 F.3d 600 (6th Cir. 1993), *cert. denied*, 115 S. Ct. 294 (1994) . . 8, 20

Brown v. Gardner, 115 S. Ct. 552 (1994) 22

Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) . . . . . *passim*

Duvall v. Bristol-Myers Squibb Co., No. 94-1520 (4th Cir.) 26

Freightliner Corp. v. Myrick, 115 S. Ct. 1483 (1995) . 20

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) . . 10, 21

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 204 Ill. Dec. 744 (Ill. App. 1994) 21, 22

Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990) 15

Jarecki v. G.D. Searle & Co., 367 U.S. 303 (1961) . . 22

Kemp v. Pfizer, Inc., No. 94-1502 (6th Cir.) 20

Khan v. Shiley, No. 50 52 48 (Orange Cty. Sup. Ct. July 9, 1993) 20

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 10, 13, 21

Lohr v. Medtronic, Inc., 1995 WL 360472 (11th Cir. July 3, 1995) 25

Martello v. Ciba Vision Corp., 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) 17

Mulligan v. Pfizer, Inc., 850 F. Supp. 633 (S.D. Ohio 1994) 24, 25

New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544, 384 A.2d 795 (1978) 24

New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 115 S. Ct. 1671 (1995) 16, 23

Reiter v. Zimmer, 830 F.Supp. 199 (S.D.N.Y. 1993) . 17

Reno v. Koray, 115 S. Ct. 2021 (1995) 22

Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) . . 21

Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993) 10, 13, 21

Talbott v. Bard, No. 94-1951 (1st Cir.) 26

Virginia Military Institute v. United States, 113 S. Ct. 2431 (1993) 12

STATUTES AND REGULATIONS

21 U.S.C. § 360e 2, 22

21 U.S.C. § 360e(d)(2)(A) 22

21 U.S.C. § 360e(d)(2)(B) 22

21 U.S.C. § 360h(a) 15, 16, 24, 25

21 U.S.C. § 360h(b) 24, 25

21 U.S.C. § 360h(c) 24, 25

21 U.S.C. § 360h(d) 15, 24, 25

21 U.S.C. § 360k 9, 23

21 U.S.C. § 360k(a) . . . . . *passim*

21 U.S.C. § 360k(a)(1) 16

21 U.S.C. § 360k(a)(2) 10, 11, 14, 15

21 U.S.C. § 360k(b) 23

21 C.F.R. § 808.1(d) 26

21 C.F.R. § 808.1(d)(1) 26

21 C.F.R. § 808.1(d)(2) 17

21 C.F.R. § 808.1(d)(6)(ii) 24

21 C.F.R. § 808.20(a) 23

21 C.F.R. § 808.20(c)(1) 24

LEGISLATIVE HISTORY

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 23

MISCELLANEOUS

Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1995) 22

Javitt, *I've Got You Under My Skin--And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 Food & Drug L.J. 553 (1994) 21

R. Stern, et al., *Supreme Court Practice* (7th ed. 1993) 12

Van Der Graff, *et al.*, *Risk of Strut Fracture of Bjork-Shiley Valves*, 339 The Lancet (Feb. 1, 1992) 8

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

No. 94-1971

SHILEY, Inc.; Hospital Products Group, Inc.
(formerly Howmedica, Inc.); Pfizer, Inc.

Petitioners,

v.

NINA MICHAEL,

Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

The case arises from injuries suffered by respondent Nina Michael as a result of the Bjork-Shiley Convexo-Concave heart valve ("C-C valve"). Respondent's doctors prescribed the C-C valve in reliance on petitioners' advertisements that deceived them into believing that the C-C valve was an appropriate treatment for respondent's ailment. After the valve had been implanted in respondent, evidence that the valve has a tendency to fracture while implanted in the chests of its patients, causing hundreds, if not thousands, of deaths and debilitating injuries, became public, as did the fact that petitioners concealed this evidence. After

respondent learned the truth about her C-C valve, her doctors took the unusual step of recommending that the C-C valve be explanted and replaced with a mechanical valve manufactured by a different company.[1]

In a narrow opinion, the contours of which were shaped by the unique facts of this case, the court of appeals held that the preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), preempted all but two of respondent's state-law damages claims. The court held that respondent's claims based on petitioners' fraudulent promotion of the C-C valve to respondent's doctors and breach of express written warranty were not preempted because neither of those claims would establish state-law requirements "different from, or in addition to" MDA requirements, as 21 U.S.C. § 360k(a) demands. In finding these claims not to be preempted, the court of appeals faithfully applied the analysis set forth in this Court's recent decisions in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995), and *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

At bottom, petitioners' position is that, because the Food and Drug Administration ("FDA") gave them permission to market the C-C valve under the MDA's premarket approval provision, 21 U.S.C. § 360e, petitioners are immune from liability for respondent's breach of warranty claim created by petitioners' own contractual undertakings, and respondent's claim that she and her doctors were induced fraudulently to select petitioners' valve instead

---

[1] Petitioner Shiley, Inc., the company that made the C-C valve, is a wholly-owned subsidiary of petitioner Pfizer, Inc. Petitioner Hospital Products Group, Inc. (formerly Howmedica, Inc.) is the division of Pfizer to which Shiley reported. For convenience, we generally refer to the companies collectively as "petitioners," although we recognized that each of them did not participate in every decision described below.

of a valve made by a competitor. The Third Circuit properly rejected the extreme approach put forward by petitioners, holding that neither the MDA nor its legislative history support the position that respondent's claims are preempted. As shown below, the decision of the court of appeals creates no conflict among the circuits and is fully consistent with the decisions of this Court. Therefore, review should be denied.

STATUTES AND REGULATIONS INVOLVED

The principal statutes and regulations involved in this case are reproduced in the appendix to this Opposition ("Resp. App.").

STATEMENT OF THE CASE

The history of the C-C valve is unique among medical devices. Yet, the petition creates the false impression that the decision of the court of appeals will have an important impact because the C-C valve was just another medical device that suffered from a few mechanical failures but generally complied with all legal requirements and caused little or no harm. Only by distorting the facts can petitioners hope to persuade this Court that the MDA's preemption provision should be applied to claims for deliberate deception of respondent's physicians outside of, and unrelated to, petitioners' FDA filings, and for breach of an express written warranty that petitioners voluntarily offered to respondent.

To show the unlikelihood that this case will ever be replicated, we first chronicle the unusual history of the C-C valve. Next, we discuss respondent's highly personal decision to remove the valve and replace it with a safer valve. Thereafter, we provide a brief description of respondent's lawsuit and the decisions below.

A. The History Of The C-C Valve

Mechanical heart valves, such as the C-C valve, are surgically implanted in individuals whose natural heart valves are not properly regulating their blood flow. The C-C valve consists of a metal disk inserted into a circular ring. The disk is attached to the ring by two sets of metal struts, one of which is integral to the ring and the other of which is welded to the ring. When the C-C valve is functioning, the blood flows from the heart through the ring, and the disk moves back and forth to regulate the flow. Unfortunately, because of serious, documented design and manufacturing defects in the C-C valve, the welded strut has a tendency — unique among mechanical heart valves — to fracture (2a). Fracture causes the disk eventually to break off from the ring, resulting in catastrophic failure and, in two out of three reported cases, patient death.[2]

In 1979, the FDA approved the C-C valve for commercial distribution. Although the FDA was aware at that time that one strut fracture had occurred during clinical trials, petitioners had described that incident as an "anomaly." House Report at 2, App. 380. In fact, however, petitioners failed to report that three strut fractures had occurred while petitioners' investigational device applications — a precursor to full commercial approval — were pending. House Report at 17-18, App. 395-96.

Moreover, 18 strut fractures had occurred in pre-clinical testing of the valve, the first occurring "as early as

---

[2] "The Bjork-Shiley Heart Valve: 'Earn As You Learn,'" Report of the Subcommittee on Oversight and Investigations of the Energy and Commerce Committee of the U.S. House of Representatives (hereafter "House Report"), at 46, Third Circuit Appendix ("App.") 422.

May 1975."[3] Petitioners did not disclose these fractures until October 1985, after the devices had been implanted in almost all of its victims (including respondent), as part of a "data dump" on the FDA of more than 300 documents. Task Group Report at 24, App. 452. Shortly after the fractures began to occur, the device's principal designer, Dr. Viking Bjork, told petitioners' executives that the valve should no longer be marketed because it was "evident . . . that the manufacture of the prosthetic valve is not acceptable," and that the only solution was producing a valve without a welded strut. Shockingly, petitioners told Dr. Bjork not to publish his data concerning strut fractures, which would have alerted the medical community to the problem, because they expected "a few more" to occur. App. 548; *see* 33a.

In a 1983 paper written by Howmedica, petitioners belatedly conceded that their 29 millimeter valve — which has a particularly high fracture risk and is the type implanted in respondent — was poorly designed. House Report at 8, App. 386. Compounding the problems resulting from the valve's faulty design were petitioners' abysmal manufacturing processes. Howmedica's 1983 report found poor controls in the measurement of the C-C valves and in welding and little or no commitment to quality control. House Report at 8, App. 386. Howmedica further reported that Shiley's welding

---

[3] *See* R.M. Johnson, *et al.*, "Report of the Shiley Task Group" (Dec. 1990) (hereafter "Task Group Report"), at 4-5, App. 432-33. The Task Group Report was based on a FDA study which concluded that petitioner "Shiley, Inc. has engaged in a continuing scheme to interrupt, deflect, and misdirect FDA's regulation of the Shiley Convexo-Concave heart valve." *Id.* at 2, App. 430. The Report also determined that it was likely that Shiley had engaged in criminal activity and urged that the case be transmitted to the Department of Justice for investigation by a grand jury. *Id.; see also id.* at 455 (discussing attempts to "obstruct justice" and "possibility of extreme criminal conduct").

practices were "out of control [and] not monitored," "that there [was] non uniformity of weld pattern," that poorly designed valves were being shipped for distribution, and that other significant problems existed. *Id.* Inspections of petitioners' manufacturing plants uncovered disgraceful conditions, including evidence of untrained welders, a lack of standard manufacturing procedures, and a failure to document device problems and failures. *See* House Report at 7-11, App. 387-91. Finally, as the Third Circuit explained in some detail, petitioners' management directed Shiley employees to cover up defects and strut cracks by re-welding weak struts and polishing out cracks, which further undermined the already precarious structural integrity of the valves, and deceived patients and their treating physicians about the true condition of the valves. JA 555-557, 613-17, 625-29, 635-36, *discussed in* 33a.

Despite their knowledge to the contrary, petitioners undertook a two-pronged effort throughout the 1980's to deceive the medical community — including specifically respondent's physicians (*see* 36a) — into believing that the C-C valve was safe. In "Dear Doctor" letters and other direct communications to physicians, including advertisements that were never reviewed by the FDA, House Report at 15-16, App. 393-94, petitioners misrepresented the true number of fractures and claimed that only a few fractures were expected in the future, when it had no basis for making such statements (33a). Second, petitioners told doctors falsely, with the intent to deceive, that the fracture problem, underreported as it was, was outweighed by an alleged thromboembolic advantage, *i.e.*, that the C-C valve experienced fewer blood clotting problems than did its

competitors. In fact, this so-called "advantage" did not exist. House Report at 15-17, App. 393-95.[4]

In February 1990, the Committee on Energy and Commerce of the U.S. House of Representatives held hearings on the C-C valve fiasco. The hearings made public the valve's design and manufacturing problems and petitioners' efforts to conceal them from the medical community. *See generally* House Report, App. 379-427. Less than a month later, on March 21, 1990, petitioners asked the FDA to withdraw its premarket approval, and the FDA did so nine days later (41a-42a).

Thus, despite petitioners' best efforts to prevent the medical community and patients from learning the truth, the C-C valve's high fracture rates gradually became known to physicians and the public. By early 1990, 389 fractures had been reported, 248 of which resulted in death. House Report at 45-46, App. 421-22. Moreover, because the signs and symptoms of imminent valve failure are similar to those of other cardiac problems, and because many patients with C-C valves died without autopsy, the actual number of fractures is estimated to be at least two to three times the number reported.[5]

---

[4] In finding that respondent had produced sufficient evidence to proceed to trial on her fraud claim, the Third Circuit briefly summarized petitioners' deception with respect to its claim of thromboembolic advantage (33a). Above all else, it was the company's deception in this regard that kept the valve on the market, misled the medical community, and led to needless deaths and injuries. *See* Task Force Report at 15-18 (describing "the Thromboembolic Advantage Pretense"), App. 443-46.

[5] Through January 11, 1990, an additional 553 "hidden fractures" were estimated, although petitioners did not include these fractures in their "Dear Doctor" letters. House Report at 47-48, App. 423-24.

Then, a January 1992 study of over 2,300 Dutch C-C valve patients found that the cumulative incidence of strut fractures in the type of valve implanted in respondent is a dangerously high 4.2 percent, rising to 6.3 percent in individuals, such as respondent, under age 50.[6] Indeed, petitioners themselves wrote respondent's physician in June 1992, stating that the fracture risk for respondent's valve was an astounding 1.09 percent *per year*, and that her valve type had been recalled in 1983, less than one year *after* respondent received the implant. App. 675.

It is against this backdrop that Nina Michael decided, on the advice of her physicians, to have her valve surgically removed and replaced. Michael Dep. at 87-122, App. 238-43. One can only imagine the emotional distress faced by respondent in weighing the risk of valve replacement surgery against the risk of keeping the potentially deadly C-C valve in her chest. Although the petition (at 5-6) belittles respondent's claim on the ground that her valve never fractured, petitioners conveniently ignore the fact that, in 1992, they entered into a worldwide class action settlement in which, among other things, they agreed to pay for explantation surgeries for patients carrying high-risk C-C valves.[7]

---

[6] Van Der Graff, *et al.*, *Risk of Strut Fracture of Bjork-Shiley Valves*, 339 The Lancet 257-61 (Feb. 1, 1992), *in* App. 669-73. The Dutch study concluded that prophylactic replacement of the C-C valve should be considered in patients, like respondent, with large 60 degree C-C mitral valves. *See* App. 477 (deposition testimony of respondent's physician indicating reliance on Dutch study).

[7] *See Bowling v. Pfizer*, 143 F.R.D. 141, 149, 166 (S.D. Ohio 1992), *appeal dismissed*, 14 F.3d 600 (6th Cir. 1993), *cert. denied*, 115 S. Ct. 294 (1994). In addition, on June 30, 1994, petitioners settled massive civil fraud claims under the False Claims Act with the United States government. Under that

(continued...)

B. Respondent's Lawsuit And The Decisions Below

In March 1993, respondent filed suit in Pennsylvania state court on theories of negligent manufacture and design, strict product liability, breach of implied warranty of merchantability, breach of an express warranty, and common-law fraud (on respondent, her doctors, and the FDA)(1a-2a). She sought recovery for the medical expenses and pain and suffering associated with removal of the C-C valve, for lost wages, and for emotional distress associated with her years of living with the threat that the valve inside her chest might fracture. Complaint, ¶¶ 30-33, 46-48, App. 22, 26-27; *see* 30a (noting causal relationship between breach of warranty and respondent's damages). Petitioners removed the suit to the United States District Court for the Eastern District of Pennsylvania based on diversity jurisdiction.

The district court dismissed respondent's claims on the ground that they were preempted by the MDA and that she had not produced sufficient evidence to state a claim under Pennsylvania law (39a-66a). The district court held that respondent's state-law claims would establish "requirements" "different from, or in addition to" federal requirements established when the FDA gave the C-C valve premarket approval in 1979. Therefore, the district court

---

[7](...continued)
settlement, petitioners paid a $10.75 million fine, and agreed to reimburse the government for all past and future medical costs associated with C-C valve fractures and qualifying valve replacement surgeries which have been, or are in the future, incurred by Medicare, Medicaid, the Veterans Administration, and any other federal program. Settlement Agreement Between United States of America, and Shiley Incorporated and Pfizer, Inc., dated June 30, 1994.

held, her claims were preempted under 21 U.S.C. § 360k(a), the MDA's preemption provision.[8]

The court of appeals affirmed in part and reversed in part (1a-38a). Relying on its prior decision in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), and the decisions in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), the Third Circuit affirmed the district court's preemption rulings as to negligence, strict liability, breach of implied warranty, and fraud on the FDA (13a-14a, 22a-24a). The Third Circuit reversed, however, the district court's rulings on express warranty and fraud on respondent's doctors, holding that the MDA did not preempt those claims (14a-21a, 24a-27a).

As to express warranty, the court relied on this Court's recent decisions in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), and in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995). In both of those cases, damages actions based on express warranty and contract theories were held not to be preempted because the duties that the plaintiffs were seeking to enforce were imposed not by "state law," as the preemption statute provided, but by agreement of the contracting parties (16a-18a). Thus, the court of appeals held that because respondent's "contract claim . . . is not state imposed — the *sine qua non* of preemption under § 360k," it is not preempted (21a).

As to the claim that petitioners fraudulently promoted the C-C valve to respondent's doctors, the court of appeals relied again on *Cipollone*, which held that claims grounded in fraud and misrepresentation were not preempted because they were not state-law "requirements" regarding the

---

[8] 21 U.S.C. § 360k is reproduced in the appendix to this Opposition at Resp. App. 1a.

advertising and labeling of cigarettes, but rather concerned a *general* state-law duty not to deceive (25a). Because respondent's fraud claim concerned petitioners' deceptive use of "Dear Doctor" letters and medical journal advertisements, it was grounded in the general duty not to deceive, rather than in the "safety and effectiveness" of the device, as 21 U.S.C. § 360k(a)(2) requires (25a-26a). Similarly, the court of appeals held that respondent's fraud claim was not "different from or in addition to . . . any other matter included in a [MDA] requirement applicable to the device." 21 U.S.C. § 360k(a)(2). Petitioners' deceptive promotional activities were not, the Third Circuit held, subject to any FDA requirements or approvals and were voluntarily undertaken without significant FDA oversight (26a-27a). Thus, the fraud claim was not preempted.

The court of appeals then held, based on much of the evidence of deceit detailed above in Part A, that there was more than sufficient evidence under state law for the express warranty and fraud claims to proceed to trial (27a-37a). The court therefore remanded those claims for further proceedings (38a). Petitioners' request for rehearing and rehearing en banc was denied on March 7, 1995, with one judge voting to rehear the case (67a).

REASONS FOR DENYING THE WRIT

The decision of the court of appeals preempting some of respondent's personal-injury claims, but allowing others to go forward, is not a proper vehicle for considering whether the MDA preempts state-law damages claims. The decision below was a product of the unique factual setting here — petitioners' express written warranty and their direct communications to doctors in advertisements and promotional materials that were never submitted to the FDA and were unrelated to obtaining and maintaining premarket approval under the MDA. Further, there is no clear split among the federal appeals courts concerning the state-law damages

claims presented in the petition (fraud and express warranty), and the decision below is fully consistent with this Court's preemption decisions.

Moreover, as a result of petitioners' own request, the FDA withdrew its marketing approval of the valve prior to the filing of respondent's suit and, indeed, prior to the open-heart surgery to remove her fracture-prone valve, for which she seeks redress. Preemption surely should not apply where the FDA's regulatory approval is no longer in effect.

Finally, although not embraced in its entirety by the court of appeals, compelling evidence of Congressional intent demonstrates that 21 U.S.C. § 360k(a) was not meant to reach *any* state-law damages claims, including, therefore, the two claims which petitioners are challenging in this Court based on the fraud and breach of warranty that the evidence establishes here. This provides another ground for denying review, since, *a fortiori*, it confirms the correctness of the Third Circuit's decision on the fraud and express warranty claims.

A. The Decision Below Is Not In Conflict With Decisions Of This Court and There Is No Significant Conflict Of Lower Court Authority.

The court of appeals held that respondent's cause of action based on petitioners' fraudulent promotion of the C-C valve and her express warranty claim were not preempted. Ignoring the fact that the Third Circuit's decision is interlocutory, and thus not ordinarily subject to review in this Court, *see generally* R. Stern, et al., *Supreme Court Practice* 195-98 (7th ed. 1993); *see also Virginia Military Institute v. United States*, 113 S. Ct. 2431, 2432 (1993)(opinion of Scalia, J., respecting the denial of certiorari), petitioners argue that the ruling below warrants review because it is contrary to prior decisions of this Court and created a serious split in circuit court authority. As we now show, with

respect to both causes of action, petitioners are incorrect, and there is no need for review by this Court.

1. Fraudulent Promotion of the C-C Valve. In holding that the MDA does not preempt respondent's fraud claim, the court of appeals described in detail petitioners' systematic attempt to deceive respondent's doctors and others in the medical community about the risks and benefits of the C-C valve (31a-37a), which is the core of respondent's fraudulent promotion claim. Petitioners assert that the court of appeals' decision on this claim conflicts with the First Circuit's decision in *King*, 983 F.2d 1130, and the Fifth Circuit's decision in *Stamps*, 984 F.2d 1416. In fact, as the court of appeals held, its "conclusion does not conflict with the . . . determination in *King*" (27a), and the decision in *Stamps* is inapposite.

The fraud claim in *King* was expressly based on the "absence of warnings on the medical device" (27a). In the First Circuit's view, the claim was therefore a disguised failure-to-warn claim. Because that court held that a failure-to-warn claim was preempted as "different from, or in addition to" to the device's FDA-approved labeling, it held that the fraud claim was preempted as well. *King*, 983 F.2d at 1136; *see also id.* at 1139-40 (concurring opinion of Aldrich, J., and Campbell, J.).

In contrast, here, as the Third Circuit noted (27a), the fraud claim is premised solely on petitioners' false and misleading statements concerning the C-C valve. Respondent did not base this cause of action on a product liability defect or a failure-to-warn theory. Put simply, respondent's fraud allegations in this case have nothing to do with what should or should not have been on the C-C valve's label, and thus the Third Circuit's decision permitting that claim to proceed does not conflict with *King*. And, in *Stamps*, the Fifth Circuit did not even reach the plaintiff's fraud claim because the claim had not been properly pled in the complaint. 984 F.2d at 1422 n.5. Only by ignoring that crucial fact, and

equating a fraud claim with a duty-to-warn claim — which *Stamps* did find preempted — can petitioners make the attenuated argument that *Stamps* and the decision below are in conflict.

Nor are petitioners correct that the court of appeals misapplied this Court's case law in evaluating the fraud claim. The Third Circuit correctly interpreted *Cipollone*, which considered the preemptive effect of the Public Health Cigarette Smoking Act of 1969 on a variety of damages claims raised by a smoker who died from using the defendants' products. Section 5(b) of the Act provided that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 112 S. Ct. at 2617. Section 4 of the Act mandated a specific warning for all cigarette packaging. *Id.* at 2616.

Cipollone held that because duty-to-warn claims could create state-imposed tort liability for failure to give a warning over and above the warning required by Congress, those claims were preempted. *Id.* at 2621. But other claims — fraudulent misrepresentation, conspiracy to misrepresent or conceal facts, and breach of warranty — were not preempted because, although they dealt with "smoking and health" in some sense, they were grounded in either a general tort duty not to deceive, or a contractual relationship between the parties. *Id.* at 2623-24 & n.27.

Similarly, as the Third Circuit held (25a), respondent's fraud claim does not, under 21 U.S.C. § 360k(a)(2), "relate to the safety and effectiveness of the device" or to any other MDA requirement, but is grounded, as in *Cipollone*, in a duty not to deceive. Thus, to prove fraud liability, respondent will have to show that she (or her doctors) used the C-C valve in justified reliance on petitioners' deceitful statements outside the labeling context — for example, their knowingly false statements regarding the fracture rate or

regarding thromboembolic advantage. Despite petitioners' protestations to the contrary, respondent's fraud claim is not premised on whether the valve was unsafe or ineffective or its warning labels inadequate.

Nor do the facts that the FDA has the power to require new device labeling to be submitted and to order manufacturers to notify the public of device problems mean that respondent's fraud claim related to other matters "applicable to the device under this chapter." 21 U.S.C. § 360k(a)(2); *see* Pet. 18. The FDA has never, to respondent's knowledge, pre-approved magazine advertisements as device labeling, and nothing in the regulations cited by petitioners suggests otherwise. Pet. 18-19. Accordingly, the FDA did not require petitioners to submit copies of proposed advertising of the C-C valve. And no such MDA requirements "*applicable* to the device" concern petitioners' alleged deceit, as is necessary for preemption under 21 U.S.C. § 360k(a), as the Third Circuit correctly held (26a-27a). As to the FDA's power to require notification to doctors and patients under 21 U.S.C. § 360h(a), even assuming that power has any preemptive effect — which, in our view, it does not — it relates to a state-law duty-to-warn claim, not to whether petitioners affirmatively committed fraud on the medical community by issuing false and misleading advertisements and letters.[9]

In an effort to escape the holding of *Cipollone*, petitioners claim that the court of appeals should have relied on purportedly broader preemption holdings that construe the statutory term "relate to" because that term is used in

---

[9] Petitioners reliance on 21 U.S.C. § 360h(a) is disingenuous, since they do not cite § 360h*(d)*. Under that provision, even when the FDA orders a manufacturer to provide notification under § 360h(a), such an order "shall not relieve any person from liability under Federal *or State law*" (emphasis added). *See infra* at 24-25 (discussing § 360h(d) in more detail).

§ 360k(a). Pet. 13-17 (*citing, e.g., Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990)). But as explained above, respondent's fraud claim does not "relate to" any MDA requirements, but is grounded in petitioners' deceptive conduct. To be sure, the words "relate to" can be stretched to establish a connection between any two things. But as this Court recently held in a unanimous decision involving the same ERISA preemption provision construed in *Ingersoll-Rand*, in light of the strong presumption against preemption, "[i]f 'relate to' were taken to extend to the fullest stretch of its indeterminacy, then for all practical purposes preemption would never run its course ... ." *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995)(state hospital pricing statute that applies to health insurance generally, including ERISA plans, not "relate[d] to" those plans and thus not preempted).

Finally, quite apart from the "relate to" language of § 360k(a)(2), in order to be preempted, the fraud claim must *also* be "different from, or in addition to" an FDA requirement. 21 U.S.C. § 360k(a)(1). On this score, petitioners argue only that a damages award based on fraud would somehow be different from, or in addition to, the FDA's device labeling provision and 21 U.S.C. § 360h(a). Pet. 19-20. Again, as discussed above, the FDA's regulatory authority over labels and the *potential* for FDA to require petitioners to issue a public notification are not anti-fraud provisions and have no bearing on whether petitioners affirmatively defrauded the medical community and heart valve patients such as respondent.

2. Breach of Express Warranty. Petitioners argue that the decision below conflicts with the First Circuit's decision in *King*, which preempted an express warranty claim. The court of appeals effectively demonstrated that its decision does not conflict with *King*. Since *King* did not describe the specific language of the warranty at issue there (19a), it is unclear whether the warranty was actually required by the MDA or rather, as here, a voluntary

undertaking, warranting on the device's package that "reasonable care has been used in the manufacture of this device" (6a). This point is potentially dispositive since, under *Cipollone*, such private contractual undertakings are not state-imposed "requirements" that trigger preemption. *See* 17a.

Moreover, as the court of appeals noted (21a), even if placing a warranty on the valve's packaging transformed the warranty into an MDA requirement, rather than a voluntarily undertaken obligation of the warrantor (as *Cipollone* teaches), a state-law breach of warranty finding would not be "different from, or in addition to" any MDA requirement; it would be vindication of that requirement. *See* 21 C.F.R. 808.1(d)(2)(MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act"). *King* also did not consider this alternative basis for finding that the express warranty claim was not preempted.[10]

Petitioners also assert that the court of appeals misapplied *Cipollone*'s express warranty holding. However, as in *Cipollone*, the express warranty claim here was not imposed by state law, or even by the FDA, but was voluntarily placed on the C-C valve's packaging "*by the warrantor[s]*," *i.e.*, petitioners. *Cipollone*, 112 S. Ct. at 2622 (emphasis added). Furthermore, in *Cipollone*,

---

[10] For the same reasons, the express warranty holding in *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995), is not in conflict with the decision below. Indeed, *Martello* did not separately evaluate any of the plaintiff's causes of action, and cited with approval a decision which held that a state-law claim that seeks only to vindicate federal regulatory requirements is not preempted. *Id.* at 1169 (*citing Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993)). This Court denied certiorari in *Martello* after the filing of the petition here.

"statements made in respondents' advertising," *id.* at 2622, created non-preempted, enforceable warranties, even though they were displayed in the very advertisements on which, in 1972, the Federal Trade Commission required that the federally-mandated warning be placed. *Id.* at 2617; *see id.* at 2622 ("That the terms of the warranty may have been set forth in [regulated] advertisements rather than in a separate document is irrelevant").[11]

This Court's decision last Term in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995), also supports the Third Circuit's express warranty ruling. *Wolens* held that contract claims grounded in promises made by airlines in their frequent flyer programs are not preempted by a provision in the Airline Deregulation Act that preempts state laws "related to a price, route, or service of an air carrier . . . ." *See id.* at 821 n.1. As in *Cipollone*, the Court held that contractual obligations undertaken voluntarily — like petitioners' voluntary representation that it used "reasonable care" in the manufacture of the C-C valve — were not imposed by state law, but by the parties to the contract. *Wolens*, 115 S. Ct. at 824. As in *Wolens*, respondent here seeks to do no more than hold petitioners to their bargain, "with no enlargement or enhancement based on state laws or policies external to the agreement." *Id.* While petitioners

---

[11] Petitioners' new-found claim that the Third Circuit misunderstood *Cipollone* is more than a little ironic. In the district court, petitioners had explicitly conceded that the express warranty claim was not preempted because of the holding in *Cipollone*, and thus did *not* move for summary judgment on that basis. Defendants' Motion for Partial Summary Judgment Based on Federal Preemption, at 19 n.17, App. 70. Accordingly, the district court did not specifically consider whether respondent's express warranty claim was preempted. Nevertheless, the court of appeals held that the district court had preempted all of respondent's claims and addressed the express warranty claim (14a).

are correct that their manufacturing processes might come into play in assessing the express warranty claim, the Court in *Wolens* acknowledged that airline "rates and services" — the very topics of the relevant preemption provision — would necessarily be at issue in the breach of contract suit. *Id.* But because "[a] remedy confined to a contract's terms simply holds parties to their agreements," the express warranty claim was not preempted there. *Id.* For the same reason, the express warranty claim is not preempted here, and the court of appeals' decision was correct.

B. The Unique Circumstances of Respondent's Case and the Regulatory History of the C-C Valve Make This Case A Poor Vehicle For Considering The General Scope Of MDA Preemption.

As noted above, this case turns on unique circumstances, and is not a precedent-setting ruling on the general scope of MDA preemption. As a so-called Class III medical device (*see* 3a-4a), the C-C valve was the first device after the passage of the MDA for which a medical device manufacturer sought and received premarket approval from the FDA. At that time, the agency had not formulated any specific internal rules for heart valves and had not yet established formal procedures for considering premarket approval applications (*see* 4a). Petitioners took advantage of this regulatory disarray to fraudulently promote their product during and after the FDA approval process to doctors, for whom petitioners were the sole source of information on the C-C valve (5a). Because the FDA's premarket approval procedures are now in place, it is not nearly as likely that the extreme deception of the medical community that occurred with the C-C valve — which is the basis for one of respondent's non-preempted claims — will recur in the future.

Further, as part of its marketing scheme, petitioners offered an unusual written warranty that is central to the

court of appeals' other holding concerning respondent's express warranty claim (14a-22a). That type of warranty is not likely to be offered again, which also undermines the general significance of the court of appeals' ruling.

Moreover, a ruling here would have little practical consequence for other C-C valve victims, many of whom have died or resolved their claims in a world-wide class action settlement. *See supra* at 8 & note 7. Accordingly, the vast majority of future fracture and reoperation claims are governed by that settlement and thus unaffected by the decision below. *Bowling*, 143 F.R.D. at 148-50 (describing relief in detail).

Finally, after petitioners' fraud was exposed, they asked the FDA to withdraw premarket approval of the C-C valve. In requesting the withdrawal, petitioners promised that they would "not at any time reintroduce th[eir] product into commerce in the U.S. or overseas." App. 836. On March 30, 1990, the FDA accepted the withdrawal. App. 838, *see* 41a-42a.[12] Because of this unique regulatory chronology, there is no possibility that the C-C valve will be implanted in another unsuspecting patient. In light of the overwhelming

---

[12] One court has held that the withdrawal of the C-C valve's pre-market approval vitiates any preemptive effect 21 U.S.C. § 360k(a) may have had on the fraud claim of a C-C valve victim. Order and Opinion Re Federal Preemption, *Khan v. Shiley*, No. 50 52 48 (Orange Cty. Sup. Ct. July 9, 1993), *in* App. 98. The district court disagreed (50a n.11). *But see Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995)(no preemption where federal highway safety standard no longer in effect).

The question whether preemption is applicable under the MDA where there is no extant premarket approval is squarely presented in *Kemp v. Pfizer, Inc.*, No. 94-1502 (6th Cir.), a case in which the plaintiff died when the C-C valve fractured. *Kemp* is fully briefed and will be argued to the Sixth Circuit on September 28, 1995.

evidence of petitioners' fraud and misrepresentation (27a-37a), which further distinguishes this case from a run-of-the-mill product liability action, this Court should deny review and await an MDA preemption case which presents personal-injury claims that are not clouded, as the claims here are, by the FDA's withdrawal of the device's premarket approval.

C. Because Congress Did Not Intend The MDA To Preempt Any State-Law Damages Claims, The Third Circuit's Rulings On The Fraud And Express Warranty Claims Are Plainly Correct.

Because of its prior holding in *Gile v. Optical Radiation Corp.*, 22 F.3d 540, the court of appeals was required to assume that, in enacting the MDA, Congress intended to preempt some state-law damages actions. However, as we now show, that assumption is not correct, which provides further support for the Third Circuit's decision that two of respondent's claims are not preempted.

First, the MDA's preemption provision, 21 U.S.C. § 360k(a), does not apply to all "State law" — language which *Cipollone* considered important and which reasonably may be construed to include common law. Rather, § 360k(a) states that "[n]o State or political subdivision of a State may establish or continue in effect" certain device "requirements." To equate a jury award or a court adjudication of a common law claim with a "State . . . establish[ing] or continu[ing] in effect" a device "requirement" strains ordinary English usage beyond the breaking point. *See Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 210, 204 Ill. Dec. 744 (Ill. App. 1994).[13]

---

[13] Several federal appellate courts, in addition to the Third Circuit, have held that § 360k(a) can preempt some common law claims. *See, e.g., King*, 983 F.2d 1130; *Stamps*, 984 F.2d 1416; (continued...)

Second, whether the word "requirement" covers damages actions depends on the word's context in the statute at issue. *See Brown v. Gardner*, 115 S. Ct. 552, 555 (1994) ("a word is known by the company it keeps") (citing *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)). Section 360k(a) uses "requirement" three times:

> [N]o state . . . may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to a device under this chapter (emphasis added).

The latter two uses of "requirement" in § 360k(a) are unambiguous references to the statutory and regulatory requirements imposed under the MDA, *see, e.g.*, 21 U.S.C. § 360e(d)(2)(A),(B) (premarket approval labeling requirements), not references to damages remedies or to the common law. *See Haudrich*, 642 N.E.2d at 209-10; Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 926 (1995).

The first use of "requirement" in § 360k(a), referring to actions of states and their political subdivisions that may be preempted by the MDA, is stated identically to the latter

---

[13](...continued)
Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992). But as one commentator stated, this line of "cases appear to ignore both the explicit language of the MDA and the clear legislative history leading up to that Act." Javitt, *I've Got You Under My Skin — And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 Food & Drug L.J. 553, 559 (1994).

two, and it also makes no reference to damages actions or the common law. Thus, there is no indication that Congress meant the term "requirement" to be interpreted in two different ways within a single sentence, which would be necessary to overcome "the basic canon of statutory construction . . . that identical terms within an Act bear the same meaning." *Reno v. Koray*, 115 S. Ct. 2021, 2026 (1995)(internal quotation and citation omitted). Accordingly, the types of state-law "requirements" referred to at the beginning of § 360k(a) are the same types of federal-law "requirements" referred to at the end of § 360k(a) — that is, statutes, regulations, and ordinances concerning devices, not damages remedies.

Third, the plain meaning of § 360k(a) is confirmed by its legislative history. In enacting the MDA and its preemption provision, Congress made no mention whatsoever of an intent to preempt state common-law claims. *See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. at 1681 (no preemption under ERISA of hospital cost pricing where "there is not so much as a hint in ERISA's legislative history" that Congress intended such preemption). Rather, the MDA's legislative history refers solely to the potential for preemption of state and local laws and regulations addressed specifically to medical devices. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 4, 45-46 (1976).

Fourth, subsection (b) of 21 U.S.C. § 360k — mentioned nowhere in the petition — further undermines any claim that subsection (a) preempts damages claims. Subsection (b) allows States or their political subdivisions to apply to the FDA for exemptions in order to maintain "requirements" that would otherwise be preempted under subsection (a). The language of subsection (b) parallels that of subsection (a) and allows applications only from "State or political subdivisions" to exempt "requirements" "applicable to a device for human use." The legislative history of subsection (b) is clear that exemptions may be sought for

anything preempted under subsection (a), yet that history refers only to "regulation[s]" and other positive enactments issued pursuant to state law. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Moreover, the FDA's regulations construing subsection (b) begin by stating that a "State or political subdivision may apply . . . for an exemption from any requirement it has *enacted* . . . ." 21 C.F.R. § 808.20(a) (emphasis added). The term "enacted" obviously does not refer to jury awards or common law claims.[14]

Fifth, the MDA contains another provision that, consistent with the presumption against preemption, assumes that state-law damages actions will co-exist with federal regulation of medical devices. Under 21 U.S.C. § 360h(a), (b), and (c), the FDA has the power to notify the public and health professionals of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds and reimbursements with respect to such devices. Petitioners, however, while relying on § 360h(a), Pet. 2, 18, 20, ignore subsection (d) of § 360h, which is "[o]f vast significance" to the preemption analysis. *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994). That subsection, entitled "Effect on Other Liability," provides:

---

[14] *See also* 21 C.F.R. § 808.20(c)(1) (requiring state or locality seeking exemption to submit "any statute, rule, regulation or ordinance" for which exemption is sought); 21 C.F.R. § 808.1(d)(6)(ii)(in assessing whether a state or local requirement is preempted, "the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the *statute*")(emphasis added); *cf. New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795, 813-14 (1978)(existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)).

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d)(Resp. App. 2a). Thus, section 360h(d) "specifically contemplates [actions under] state law [for] liability and damages" against manufacturers of medical devices, and "unambiguously prohibits a finding of liability pursuant to section [360h](b) and (c) from shielding a defendant from state liability and damages. . . ." *Mulligan*, 850 F. Supp. at 636; *see* 18a (Congress "gave indications in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation"); *cf. Lohr v. Medtronic, Inc.*, 1995 WL 360472, *5 (11th Cir. July 3, 1995).[15]

Sixth, the FDA — the agency charged by Congress with interpreting the MDA and implementing its preemption provision — has reasonably construed the MDA not to preempt common-law claims. For instance, FDA regulations are clear that the MDA preempts only device-specific requirements, not *general* duties such as those created by the common law:

---

[15] In *Lohr*, the Eleventh Circuit found that the plaintiffs' duty-to-warn and manufacturing defect claims were preempted by the MDA, but that their design defect claims were not preempted. 1995 WL 360472, *11-*13, *15-*16. Because *Lohr* did not involve express warranty or fraud claims, *Lohr* is not in conflict with the rulings of the court of appeals for which review is sought in the petition.

> State or local requirements are preempted only where the Food and Drug Administration has established specific counterpart requirements applicable to a particular device under the act, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(Resp. App. 3a). FDA regulations further state that section 360k(a)

> does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices . . . .

21 C.F.R. § 808.1(d)(1)(emphasis added)(Resp. App. 3a). Here, of course, respondent's claims are based on state-law duties, such as the general duty not to deceive and the duty imposed by state contract law, that "relate[] . . . to other products in addition to devices . . . . " Although not relied on by the Third Circuit, the views of the FDA provide further support for a narrow reading of 21 U.S.C. § 360k(a).[16]

---

[16] Consistent with the FDA's regulatory stance, the Justice Department recently filed amicus briefs on behalf of the FDA, stating that premarket approval requirements are not "specific requirements" with respect to a device and, therefore, do not preempt state-law damages claims, Brief for United States as Amicus Curiae in *Talbott v. Bard*, No. 94-1951 (1st Cir.), at 14 n.5, 25-26 n.7, and that express warranty claims are not preempted (continued...)

For all these additional reasons, the decision of the court of appeals is correct as to the fraud and express warranty claims and review should not be granted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

Gary Green
(Counsel of Record)
Sidkoff, Pincus & Green
1101 Market Street
2700 ARAMark Tower
Philadelphia, PA 19107
(215) 574-0600

Attorney for Respondent

August 2, 1995

---

[16](...continued)
by 21 U.S.C. § 360k(a). Brief for the Food and Drug Administration as Amicus Curiae in *Duvall v. Bristol-Myers Squibb Co.*, No. 94-1520 (4th Cir.), at 11-22.

The FDA has also issued regulatory pronouncements stating that state-law judicial remedies, such as product liability claims, are not preempted by 21 U.S.C. § 360k(a). *See* Advisory Opinion of FDA's Associate Commissioner for Regulatory Affairs, dated Mar. 8, 1984 (Resp. App. 4a-6a), *in* App. 955-59; Letter from Chief of FDA's Regulatory Staff, dated Feb. 2, 1987 ("FDA believes that section 521 [§ 360k(a)] does not preempt general product liability requirements")(Resp. App. 7a), *in* App. 961-63.

PRINCIPAL STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * *

21 U.S.C. § 360h(d) provides:

Effect on Other Liability

Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

PRINCIPAL REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regualtion of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different

from, or in addition to, any requirement applicable to such device under any rpovision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to adevice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in National Women's Health Network, et. al. v. A.H. Robins Company, Inc., No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injuctive remedies. This advisory opinion does not address

the merits of the application of such remedies in any action filed by the network in the State of Massachussets or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures